



Revised American National Standard/
American Dental Association
Standard No. 78

Dental Obturating Cones

Modified adoption of *ISO 6877:2006, Dentistry — Root canal obturating points*

ADA American
Dental
Association®
Council on
Scientific Affairs

REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 78 FOR DENTAL OBTURATING CONES

The Council on Scientific Affairs of the American Dental Association has approved revised American Dental Association Standard No. 78 for Dental Obturating Cones. 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. 78 as an American National Standard on August 12, 2013.

The ADA Standards Committee on Dental Products thanks the members of Working Group 1.5 on Endodontic Filling Materials and the organizations with which they were affiliated at the time the standard was developed:

Frank Lentine (chairman), Lentine Enterprises, Ltd., Taylor, MI;
Timothy Svec (secretary), UTDB-Houston, TX;
Gerald Glickman, Baylor College of Dentistry, Houston, TX;
Lonnie Graybill, Miltex Corp., York, PA;
Jeffrey Hutter, Boston University, MA;
John Ingle, American Association of Endodontists, Chicago, IL;
Neill Luebke, Brookfield, WI;
Randall Maxwell, Dentsply Tulsa Dental Specialties, OK;
Spiro Megremis, American Dental Association, Chicago, IL;
Michael Sobotka, Charles B. Schwed Co., Kew Gardens, NY; and
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FOREWORD

(This Foreword does not form a part of the Proposed Revision of ANSI/ADA Standard No. 78 for Dental Obturating Cones).

The previous edition of this standard, ADA Standard No. 78-2006, was an adoption of ISO 6877-1:1995, Dentistry—Root canal obturating points. This standard is a modified adoption of ISO 6877:2006, which is a revision of ISO 6877-1:1995. ADA SCDP Working Group No. 1.5 on Endodontic Filling Materials examined the international standard and found it acceptable for adoption as revised ANSI/ADA Standard No. 78. It replaces ANSI/ADA Standard No. 78-2006.

The modifications of ISO 6877:2006 for ADA Standard No. 78 are:

- ADA Standard No. 78 uses the term "cone," whereas ISO 6877 uses "point";
- ADA Standard No. 78 does not include "size designations" in the Definitions, whereas ISO 6877 includes them;
- ADA Standard No. 78 includes Materials in 4.1, whereas ISO 6877 does not include it;
- ADA Standard No. 78 does not include biocompatibility in 4.2, whereas ISO 6877 includes it;
- ADA Standard No. 78 specifies "tip design" options in 4.2.1, whereas ISO 6877 does not include them;
- ADA Standard No. 78 includes cone color consistency in 4.2.3, whereas ISO 6877 does not include it;
- ADA Standard No. 78 includes physical testing after sterilization in 4.2.4, whereas ISO 6877 does not include it;
- ADA Standard No. 78 specifies, in 4.3.3, length "to be within +/- 0.2 mm of the stated length, whereas ISO 6877, in 4.3, specifies overall length as "not less than 28 mm or not less than the stated length"; and
- ADA Standard No. 78 uses the term "Brittleness" in 6.4, whereas ISO 6877 uses the term "Physical integrity" in 4.5.

Also, in ADA Standard No. 78, 7.2 and ISO 6877, Marking, 8. f, the requirement for use of "Sterile" differs.

In ADA Standard No. 78 "STERILE" is used if the manufacturer claims that the contents of the unopened pack are sterile. In addition, on bulk packs of cones marked "STERILE," "a statement to the effect that sterility is not guaranteed after the pack is opened."

ISO 6877 uses the word "STERILE," "if the manufacturer claims that the contents of the unopened pack are sterile. In addition, on bulk packs of points marked "STERILE", a statement to the effect that sterility is not guaranteed after the pack is opened (A claim by the manufacturer that the contents of the unopened pack are sterile is the responsibility of the manufacturer. This International Standard does not specify requirements or test methods for sterility; reference should be made to any national requirements that may exist. When no national requirements exist, reference should be made to the United States Pharmacopoeia (USP) or the British Pharmacopoeia (BP). Standards on methods of validating sterilisation processes, produced by ISO/TC 198 *Sterilization of health care products*, are also available: ISO 11134, ISO 11135, ISO 11137, ISO 11737-2, ISO 13683, ISO 14160, ISO 14937)"

REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 78 FOR DENTAL OBTURATING CONES

1 SCOPE AND CLASSIFICATION

1.1 Scope

This standard specifies the dimensions and requirements for prefabricated metallic or polymeric-based cones suitable for use in the obturation of a root canal system restoration. It also specifies numerical systems and color-coding system for designating sizes.

2 NORMATIVE REFERENCES

The following documents form a part of this specification.

- 2.1 ISO 3665: 1976, Photography—Intra-oral Dental Radiographic Film—Standard
(Copies of ISO standards may be obtained from the American National Standards Institute, 25 West 43 St., New York, NY 10036; or www.ansi.org).
- 2.2 ASTM B209 Standard Standard for Aluminum-Alloy Sheet and Plate
(ASTM specifications are available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428; or www.astm.org).

3 DEFINITIONS

For the purposes of this specification, the following terms and definitions apply:

3.1 Standardized Cone

Cones having uniform standardization taper of 2% throughout all the range of sizes available.

3.2 Taper Size Cone

Cones whose sizes are determined by the tip sizes and the tapers.

3.3 Cone

Complete prefabricated metallic or polymeric dental root canal obturating cone.

3.4 Tip

The narrow end of the cone.

3.5 Unit Pack

The smallest pack that is distributed and that may contain one or more sizes of cones.

4 REQUIREMENTS

4.1 Materials

- 4.1.1 **Metal cones.** Throughout their tapered length, the cones shall be smooth, uniform in composition, without surface pitting and free from inclusions or extraneous matter. Testing shall be carried out in accordance with 5.2.