



American National Standard/
American Dental Association
Specification No. 57

Endodontic Sealing Materials

Modified adoption of ISO 6876:2000, Dental root canal
sealing materials.



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**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION
SPECIFICATION NO. 57 FOR ENDODONTIC SEALING MATERIALS**

The Council on Scientific of the American Dental Association has approved revised American Dental Association Specification No. 57 for Endodontic Sealing Materials. 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. The American National Standards Institute granted approval of Revised ADA Specification No. 57 as an American National Standard on April 25, 2000. This standard becomes effective April 25, 2001.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed: Mr. Frank Lentine (chairman), Lentine Enterprises, Ltd., Taylor, MI; Neill H. Luebke (secretary) Brookfield, WI; Preston Blann, Defense Personnel Support Center, Philadelphia, PA; T. Chang, Block Drug Co., Jersey City, NJ; Richard Geary, American Dental Association, Chicago, IL; Max Gibbs, Sybron Corp, Leander, TX; Gerald Glickman, University of Texas, Houston, TX; Lonnie Graybill, Union Broach, York, PA; John Ingle, San Diego, CA; Max Lenz, Endodent Inc., Monrovia, CA; Lorie Linn, Dentsply Endodontics, Vancouver, WA; Herbert Schilder, Boston University Medical Center, Boston, MA; Brahma Sharma, Biotrol, Louisville, CO; Michael Sobotka, Charles B. Schwed Co., Kew Gardens, NY; Lars Spangberg, University of Connecticut, Farmington, CT; Timothy Svec, University of Texas, Houston, TX; and Harmeet Walia, University of Florida, Gainesville, FL.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 57 FOR ENDODONTIC SEALING MATERIALS

FOREWORD

(This foreword does not form a part of the ANSI/ADA Specification 57 for Endodontic Sealing Materials)

With the publication of the revised ANSI/ADA Specification No. 57 in 1993, the USA expert meeting with the ISO/TC106 Subcommittee 1, Working Group 2 for Endodontic Materials proposed that the specification be used for revision to ISO 6876, Dental Root Canal Sealing Materials. The final version of the ISO revision includes many of the US proposals. Round robin testing by members of the ISO working group, including the USA, resulted in new test procedures and test molds for Setting time, Dimensional change following setting, and Solubility. Except for the items identified below, this revised specification is in harmony with the proposed ISO 6876.2.

This revision includes harmonization with the action of the ISO working group for Endodontic Materials by moving reference of biological aspects from the body of the document to the Introduction and eliminating the Type and Class distinctions. Other important changes represented in this revision are:

- inclusion of definitions for extraneous matter, mixing time, working time, and setting time;
- change "Dimensional stability" to "Dimensional change following setting";
- deletion of a requirement for disintegration;
- elimination of aluminum sheet as an option for the step wedge in Clause 5.10;
- conversion to SI units.

ANSI/ADA Specification No. 57, as revised, is in harmony with the proposed ISO 6876.2 except for the definition of Setting time. Specification No. 57 measures setting time from the start of mixing while the ISO document measures Setting time from the end of mixing. We also have retained Figures 1 and 2 showing the fixture and split mold designs. The revised ISO document eliminated these. The current ISO document includes a variety of possible editorial errors that have not been resolved at this time. Specification No. 57 is presented without these alleged errors.

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INTRODUCTION

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this Specification but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to the relevant sections of American National Standards/American Dental Association Document No. 41 for Recommended Standard Practices for the Biological Evaluation of Dental Materials.

**AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 57
FOR ENDODONTIC SEALING MATERIALS**

1. SCOPE AND DEFINITIONS

1.1 Scope

This specification is for materials used in endodontics within the tooth to seal the root canal space.

1.2 Definitions

For the purposes of this specification, the following definitions apply.

1.2.1 Extraneous Matter

Non-essential substance.

1.2.2 Mixing Time

That part of the working time required to obtain a satisfactory mix of the components.

1.2.3 Working Time

Period of time, measured from the start of mixing, during which it is possible to manipulate the dental sealer without an adverse effect on its properties.

1.2.4 Setting Time

Period of time, measured from the start of mixing, until the sealer has set according to the criteria and the conditions described in Clause 5.6.

1.2.5 Component

One of the parts which, when combined with another, forms the sealer that is inserted clinically into the root canal system.

2. NORMATIVE REFERENCES

The following documents form a part of this specification.

2.1 American Society for Testing and Material

ASTM Designation B209 Standard *Specification for Aluminum-Alloy Sheet and Plate*

2.2 United States Pharmacopoeia

(Copies available from the Drug Standards Division, OSPC, Inc., 12601 Twinbrook Parkway, Rockville, MD 26852.)

2.3 ISO 3665: 1976

Photography—Intra-Oral Dental Radiographic Film Specification

2.4 ISO 3696: 1987

Water for Analytical Use—Specification and Test Methods (Copies of ISO Specifications may be obtained from the American National Standards Institute, 11 West 42nd St., New York, NY 10036).