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Amendment 1 - June 1985

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# Australian Standard® 2762.1—1985

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## DENTAL MATERIALS ROOT CANAL FILLING Part 1—OBTURATING POINTS (CONES)

The Tariffs, Instruments, Materials and Equipment Committee of the Australian Dental Association has adopted this standard for use in connection with its program for accreditation of certified dental products, lists of which are published periodically. Enquiries regarding this program should be addressed direct to the Australian Dental Association. When used in connection with the program, the standard is known as Australian Dental Standard (ADS) 2762.1—1985.

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The following interests are represented on Committee DN/12:

- Australian Chamber of Commerce
- Australian Dental Association
- Australian Dental Standards Laboratory
- Australian Dental Trade Association
- Australian Society of Endodontology
- Dental Schools
- Department of Defence

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**AMENDMENT No 1**

to

**AS 2762, Part 1—1985**

**DENTAL MATERIALS—ROOT CANAL FILLING  
PART 1—OBTURATING POINTS (CONES)**

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**REVISED TEXT**

The 1985 edition of AS 2762, Part 1 is amended as follows; the amendment should be inserted in the appropriate place.

SUMMARY: The following section of this standard is covered by this amendment: Contents.

Published on 7 June 1985.

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**Page 4. Contents.**

*Replace* existing '4' with '5' under the caption 'Page' for the first nine headings.

**This amendment forms part of the specification on publication.**

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## PREFACE

This standard was prepared by the Association's Committee on Endodontic Materials and Instruments under the direction of the Dental Materials and Equipment Standards Committee. It is one of a series intended for use in assessing the quality of dental materials used in Australia.

In the preparation of this standard, cognizance was taken of the ISO/TC 106 draft proposals for endodontic core materials and root canal sealers.

Dental root canal filling materials are generally considered in two categories—solid obturating cones (metallic and polymeric), and sealers and pastes (setting and non-setting). This standard is thus divided into two Parts as follows:

Part 1—Obturating Points (Cones)

Part 2—Sealers and Pastes (Setting and Non-setting)

The scope of these Parts allows for commonly used obturation techniques in endodontics. Part 1 sets out a rational set of physical properties and dimensional requirements for prefabricated metallic and polymeric-based materials intended for use as cones in the obturation of the dental root canal. This standard covers two types of points—standardized and accessory points. The requirements for diameter and taper of standardized points arise from the need to align with the sizes of corresponding root canal instruments. If a manufacturer does not designate his product according to the standardized numbering system, then they are considered to be accessory points and the requirements for diameter, taper and length do not apply.

Currently available research (W.R. Moorer and J.M. Genet, Oral Surg., Vol. 53, pp 508-517, 1982) indicates a small but significant leaching of gutta-percha points. Further investigations may point to the need for the inclusion of a solubility test in a future edition.

The Australian Dental Standards Laboratory, 240 Langridge Street, Abbotsford, Victoria, 3067 has facilities for testing materials for compliance with this standard.

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SEE AMENDMENTS

No.

# STANDARDS ASSOCIATION OF AUSTRALIA

## Australian Standard for DENTAL MATERIALS—ROOT CANAL FILLING

### PART 1—OBTURATING POINTS (CONES)

#### SPECIFICATION

**1 SCOPE.** This standard specifies requirements for prefabricated metallic and polymeric-based materials intended for use as obturating points (cones) in the obturation of the dental root canal, but not for support of a coronal restoration.

**2 REFERENCED DOCUMENTS.** The following documents are referred to in this standard:

AS 1139 Intra-oral Dental X-ray Films\*

ISO Technical Report 7405, Guidelines for Biological Evaluation of Dental Materials.

ASTM D 792-66(79) Standard Test Methods for Specific Gravity and Density of Plastics by Displacement.

**3 DEFINITIONS.** For the purpose of this standard, the following definitions apply:

**3.1 Obturating point (cone)**—a prefabricated metallic or polymeric-based cone used for root canal obturation.

**3.2 End**—the broad end of the obturating point.

**3.3 Tip**—the narrow end of the obturating point.

**3.4 Unit pack**—the smallest pack which is marketed and which may contain one or more sizes of obturating points.

**3.5 Standardized obturating points**—those complying with the dimensional requirements of Clause 9.1.

**4 TEST CONDITIONS.** Unless otherwise stated, the materials shall be tested at a temperature of  $23 \pm 2^\circ\text{C}$  and  $50 \pm 5$  percent relative humidity.

**5 MATERIALS.** Metals or alloys used shall be homogeneous, free from impurities and inclusions and extraneous matter, and shall show no evidence of tarnishing or corrosion when examined visually without magnification.

Polymers used shall be made from premium quality ingredients and shall be free from impurities and inclusions which are not constituent materials.

Any additives shall be uniformly distributed throughout the obturating point and, where applicable, shall comply with the requirements for purity of pharmaceutical products required by the Commonwealth Department of Health.

**6 FREEDOM FROM TOXICITY.** The materials from which the obturating point is made shall not

cause adverse reaction when in contact with oral tissues.

NOTE: ISO Technical Report 7405 gives guidance for the biological evaluation of dental materials.

Information on the presence of any possible toxic component shall be supplied by the manufacturer to the testing authority, on request.

**7 EFFECT OF STERILIZATION.** The obturating points shall comply with the requirements of this standard after they have been sterilized according to the manufacturer's instructions.

**8 COLOUR OF POLYMERIC OBTURATING POINTS.** Where specified, the colour of polymeric obturating points shall be as indicated by the manufacturer. The colour shall be uniform for all the points in the unit pack.

#### 9 NOMINAL SIZE DESIGNATION AND DIMENSIONS.

**9.1 Size and Diameters.** The size designation for obturating points may be by word(s) and/or by a standardized numbering system as specified in Table 1. The obturating point shall be uniformly tapered for 16 mm measured from the tip and may have a blunt or rounded tip. Where the end is flattened, the faces shall be essentially parallel to the axis of the point and to each other. The flattened section shall have a length of  $4 \pm 1$  mm (see Fig. 1). If the manufacturer designates his product according to the standardized numbering system, the projected tip diameter of obturating points (designated  $d_1$ ) and the diameter 16 mm from the tip (designated  $d_2$ ) as shown in Fig. 1, shall correspond to those given in Table 1 when measured as follows:

Measure the overall length and any specified diameter, with a shadowgraph or other equipment capable of measuring to an accuracy of 0.01 mm. The obturating point shall be circular in cross-section for at least 16 mm from the tip, have a smooth surface and shall show no structural or other irregularities.

Where any surface defects (sinks, pits, voids or lumps) are observed along 16 mm from the tip of the obturating point, the diameter shall be measured at that position. This diameter shall be within  $+0$ ,  $-0.04$  mm for metal cones and  $\pm 0.04$  mm for polymeric cones of that diameter calculated using the taper measured for that obturating point.

\*In course of revision.