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DENTAL MATERIALS
ROOT CANAL FILLING
Part 2—SEALERS AND PASTES

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) 2762.2—1985.

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SEALERS AND PASTES (SETTING AND NON-SETTING)

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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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Suggestions for improvements to Australian standards, addressed to the head office of the Association, are welcomed. Notification of any inaccuracy or ambiguity found in an Australian standard should be made without delay in order that the matter may be investigated and appropriate action taken.

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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 2 sets out a rational set of performance, labelling and packaging requirements for root canal sealers and pastes which are intended to be used to fill the root canal space. It applies to setting and non-setting materials which, if manufactured to this standard, will aid a dentist to decide objectively what material will best suit his or her particular technique.

It is recognized that dimensional stability and sealability are important properties for these materials. To date, no simple performance tests have been developed which correlate to clinical performance.

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

CONTENTS

STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
DENTAL MATERIALS—ROOT CANAL FILLING

PART 2—SEALERS AND PASTES

SPECIFICATION

1 SCOPE. This standard specifies requirements for materials to be used for filling the dental root canal space with or without the aid of obturating points. It covers only materials intended for orthograde use.

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

AS 1139 Intra-oral Dental X-ray Films*

AS 2762.1 Dental Materials—Root Canal Filling, Part 1—Obturating Points (Cones)

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

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

3.1 Setting materials—materials which set within a period of 72 h from the time of mixing.

3.2 Orthograde—root filling inserted from coronal aspect.

4 TEST CONDITIONS. Unless otherwise stated, the materials shall be tested at a temperature of 23 ± 2°C and 50 ± 5 percent relative humidity.

5 MATERIALS. The components of the material shall be such that, when used in accordance with the manufacturer's instructions, the mixed materials shall be suitable for their intended use without any adverse effects on the obturating point if recommended for use with such points (see AS 2762.1).

The materials shall be prepared in accordance with good manufacturing practice and be free from extraneous material when viewed without magnification. The quality of the ingredients used in the manufacture shall comply with the requirements for purity of pharmaceutical products as required by the Commonwealth Department of Health.

6 FREEDOM FROM TOXICITY. The material shall not cause adverse reaction when in contact with organ 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 STERILITY. Where the material, as supplied, is claimed to be sterile, it shall pass the test for sterility as specified by the Commonwealth Department of Health for sterility testing of pharmaceutical products.

8 PHYSICAL PROPERTIES.

8.1 Flow. When tested in accordance with Appendix A, the material shall form a disc of diameter not less than 20 mm.

8.2 Working time (for setting materials having a working time of less than 30 min). When determined in accordance with Appendix B, the working time of the material shall be within ±10 percent of that stated by the manufacturer.

8.3 Setting time (of setting materials only). When determined in accordance with Appendix C, the setting time of the material shall be within ±10 percent of that stated by the manufacturer.

8.4 Film thickness. When tested in accordance with Appendix D, for those materials intended for use with preformed cones, the material shall form a film of thickness not greater than 50 μm.

8.5 Radiopacity. When tested in accordance with Appendix E, the material shall show a radiopacity equivalent to not less than 3 mm of aluminium.

8.6 Solubility and disintegration. When determined in accordance with Appendix F, the solubility of the material shall not exceed 4 percent by mass, and the test specimen shall show no evidence of macroscopic disintegration.

9 INFORMATION TO BE SUPPLIED BY THE MANUFACTURER. The manufacturer shall supply the following information with each pack:

(a) Instructions for use of the material including, where applicable, the method of mixing and component mixing ratio, as well as recommendations for mixing times and any other conditions applicable to the product.

(b) Recommended method for sterilization, if applicable.

(c) Principal components and active ingredients of the material.

(d) The working time (if less than 30 min) at a temperature of 23 ± 2°C and setting time of the material at a temperature of 37 ± 2°C. If a material is non-setting, the word 'non-setting' or equivalent shall be clearly stated.

(e) Indications for clinical use, including whether the material may be used with obturating points (cones), and, if the material has the potential to

* In course of revision.