AS 2265—1983

Australian Standard®

SURGICAL IMPLANTS—ACRYLIC RESIN CEMENTS, FOR USE IN SURGERY

This Australian standard was prepared by Committee MD/3, Surgical Implants. It was approved on behalf of the Council of the Standards Association of Australia on 27 July 1983 and published on 7 October 1983.

The following interests are represented on Committee MD/3:

Australian Chamber of Commerce
Australian Orthopaedic Association
Bureau of Steel Manufacturers of Australia
Confederation of Australian Industry
Department of Defence
Department of Health
Metal Trades Industry Association of Australia
Plastics Institute of Australia Incorporated
Royal Australasian College of Surgeons
Royal Newcastle Hospital
Royal Perth Hospital
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PREFACE

This standard was prepared by the Association's Committee on Surgical Implants, under the authority of the Medical Materials and Equipment Standards Committee, as one of a series of standards for surgical implants, which will implement, for Australian purposes, International standards emanating from ISO/TC 150, Implants for Surgery. It supersedes AS 2265, Part 1—1979.

Unlike AS 2265, Part 1—1979, which dealt only with orthopaedic applications, this edition also incorporates requirements for neurosurgical applications.

The requirements specified for orthopaedic applications are technically identical with ISO 5833/1, Implants for Surgery—Acrylic Resin Cements—Part 1: Orthopaedic Applications, except for the following:

(a) The ISO property 'intrusion' has been renamed 'plasticity of dough'.

(b) In measuring compressive strength, the test specimens are conditioned at 23 ± 2°C for 24 ± 2 h.

(c) A test for sterility has been included as Appendix A.

(d) The definition for doughing time has been altered.

(e) Where there is an optional addition of radiopaque material, the cement must still comply with the requirements specified.

(f) A requirement has been added to Clause 10 in that the entire contents of the unit pack should be mixed to achieve the recommended proportions.

Several other minor changes designed to clarify procedures without altering the technical sense have also been made.

The requirements specified for neurosurgical applications are technically identical with the proposed Part 2 of ISO 5833 and contained in ISO/DP 5833/2, except that the requirement for handling time has been deleted as the test method is very subjective.

Several other minor changes arising from the need to combine the two documents into the one standard have also been made.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
SURGICAL IMPLANTS—ACRYLIC RESIN CEMENTS, FOR USE IN SURGERY

1 SCOPE. This standard specifies composition, physical performance and packaging requirements for self-curing resins based on poly (methyl methacrylate) used for the fixation of internal orthopaedic endoprostheses or for use in neurosurgery.

2 FIELD OF APPLICATION. This standard is intended to be used for the purpose of maintaining the uniformity of the product. The results obtained from the tests prescribed herein may not directly correlate with the performance of the product when placed in the human body.

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

3.1 Unit pack—one package or vial of pre-weighed powder component and one package or vial of pre-measured liquid component, together with any packages of radiopaque additives where such additives are packaged separately.

3.2 Doughing time—the time after commencement of mixing at which the mixture ceases to adhere to a standard probe (see Clause 7.4).

3.3 Setting time—the time measured from the beginning of the mixing until the time where the temperature of the polymerizing mass is midway between the ambient temperature and the maximum temperature of the exothermic reaction (see Clause 7.6).

3.4 Exothermic temperature—the maximum temperature of the mixture due to self-curing in a standard mould (see Clause 7.5).

3.5 Plasticity of dough—the depth of intrusion of the dough into a standard mould under load (see Clause 7.7).

3.6 Indentation—the penetration value in a one day old specimen derived from dial gauge readings on a Rockwell hardness tester (see Clause 7.9).

3.7 Recovery—the percent change in penetration upon removal of the major indentation load (see Clause 7.9).

4 COMPOSITION.

4.1 Basic requirement. While a variety of copolymers and comonomers may be incorporated, the set cement shall contain poly (methyl methacrylate) as its main ingredient.

4.2 Classification.

Class 1—Acrylic Bone Cement

Class 2—Neurosurgical Cement

Type 1—Slow Setting
Type 2—Fast Setting

5 PHYSICAL REQUIREMENTS.

5.1 Liquid component.

5.1.1 *Appearance*. When viewed against an illuminated screen, the liquid shall be clear and free of any particulate matter or sediment.

5.1.2 *Stability*. When tested in accordance with Clause 7.3, the liquid shall show no turbidity or deposit.

5.1.3 *Sterility*. When the liquid component is tested for sterility in accordance with Appendix A, the liquid shall comply with the criteria therein.

5.2 Powder component.

5.2.1 *Appearance*. The powder shall be pourable and free from extraneous materials such as dirt or lint.

5.2.2 *Sterility*. When the powder component is tested for sterility in accordance with Appendix A, the powder shall comply with the criteria therein.

5.3 Powder/liquid mixture. When determined by the relevant method in Clause 7, the properties of the powder/liquid mixture shall be in accordance with the values specified in Table 1. The results obtained in all determinations of doughing time and setting time shall not vary by more than 2 min.

Where there is an optional addition of radiopaque material, the mixture shall still comply with the requirements of Table 1.

TABLE 1

PROPERTIES OF POWDER/LIQUID MIXTURE

	Maximum doughing time	Setting time range	Maximum exothermic temperature	Plasticity of dough (minimum intrusion)
Class 1	5.0 min	4 to 15 min	90°C	2.0 mm
Class 2				
Type 1	6.0 min	14 to 20 min	80°C	—
Type 2	3.0 min	4 to 12 min	90°C	