AS 5833—2005

Australian Standard™

Implants for surgery—Acrylic resin cements

This Australian Standard was prepared by Committee HE-012, Surgical Implants. It was approved on behalf of the Council of Standards Australia on 10 August 2005. This Standard was published on 20 September 2005.

The following are represented on Committee HE-012:

Australian College of Operating Room Nurses
Australian Industry Group
Australian Orthopaedic Association
Australian Society for Biomaterials
Commonwealth Department of Health and Ageing
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Australian Standard™

Implants for surgery—Acrylic resin cements

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-012, Surgical Implants to supersede AS 2265—1983, *Surgical implants—Acrylic resin cements, for use in surgery*. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

The objective of this revision is to update requirements for acrylic resin cements as specified in the 2002 edition of ISO 5833.

The Standard has been reproduced from, and is identical to, ISO 5833:2002, *Implants for surgery—Acrylic resin cements.*

As this Standard is reproduced from an international Standard, the following modifications apply:

(a) Its number does not appear on each page of the text, and its identity is shown only on the cover and title page.

(b) In the source text, ‘this International Standard’ should read ‘this Australian Standard’.

(c) A full point should be substituted for a comma when referring to a decimal marker.

The term ‘normative’ has been used in this Standard to define the application of the annex to which it applies. A ‘normative’ annex is an integral part of a Standard.

CONTENTS

Annexes

NOTES

AUSTRALIAN STANDARD

Implants for surgery—Acrylic resin cements

1 Scope

This International Standard specifies the physical, mechanical, packaging and labelling requirements for curing polymerizing radio-opaque and non-radio-opaque resin cements based on poly(methacrylic acid esters). It applies to two types of cement, intended respectively for use with a syringe or in the dough state, for the fixation of internal orthopaedic prostheses and supplied as units containing premeasured amounts of sterile powder and of sterile liquid in forms suitable for mixing at the time of implantation.

This International Standard does not cover the hazards associated with the use of the cement in respect of either the patient or the user of the cement.

All requirements apply to, and all tests are intended to be performed on, the sterile product.

2 Term and definition

For the purposes of this International Standard, the following term and definition apply.

2.1

unit of cement

one package or vial of sterile premeasured powder component and one package or vial of sterile premeasured liquid component

NOTE For cements in which the radio-opaque agent is supplied separately, the unit of cement includes the vial or package of premeasured radio-opaque powder component.

3 Liquid component

3.1 Appearance

When inspected by normal or corrected vision, the liquid component shall be free from particles and other contaminants.

3.2 Stability

When tested as described in annex A, the flow time of the samples of liquid component shall not increase by more than 10 %.

3.3 Accuracy of contents

When measured to an accuracy of $\pm$ 0,1 ml, the volume of the liquid component of each of five units shall be within 5 % of that stated on the package [see 9.1 b)].