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**Implants for surgery — Acrylic resin cements**

*Implants chirurgicaux — Ciments à base de résine acrylique*



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## Contents

	Page
1 Scope .....	1
2 Definition .....	1
3 Liquid component .....	1
4 Powder component .....	1
5 Liquid-powder mixture intended for syringe usage .....	1
6 Liquid-powder mixture intended for use in dough state .....	2
7 Set and cured cement .....	2
8 Packaging .....	2
9 Labelling .....	2
<b>Annexes</b>	
A Method for determination of stability of liquid component .....	5
B Method for determination of doughing time of liquid-powder mixture of cement intended for dough usage .....	6
C Method for determination of maximum temperature and setting time of liquid-powder mixture .....	7
D Method for determination of intrusion of liquid-powder mixture of cement intended for dough usage .....	10
E Method for determination of compressive strength of cement .....	12
F Method for determination of bending modulus and bending strength of cement .....	15

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 5833 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Sub-Committee SC 1, *Materials*.

This first edition of ISO 5833 cancels and replaces the first edition of ISO 5833-1, published in 1979 and the planned ISO 5833-2, of which it constitutes a minor revision.

Annexes A, B, C, D, E and F form an integral part of this International Standard.

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# Implants for surgery — Acrylic resin cements

## 1 Scope

This International Standard applies to radio-opaque and non-radio-opaque cements and specifies physical, mechanical, packaging and labelling requirements for self-curing resin cement based on poly(methacrylic acid esters), of two types intended respectively for use with a syringe or in the dough state for the fixation of internal orthopaedic prostheses and supplied as units containing pre-measured 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 to be performed on, the sterile product.

## 2 Definition

For the purposes of this International Standard, the following definition applies.

**2.1 unit of cement:** One package or vial of sterile pre-measured powder component and one package or vial of sterile pre-measured liquid component.

## 3 Liquid component

### 3.1 Appearance

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

### 3.2 Stability

When tested as described in annex A, the flow time of either sample of liquid 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 and every one of five units shall be within 5 % of that stated on the package [see 9.1 a)].

## 4 Powder component

### 4.1 Appearance

When inspected by normal or corrected vision, the powder shall be free from agglomerates and extraneous material.

### 4.2 Accuracy of contents

When weighed to an accuracy of  $\pm 0,1$  g, the mass of the powder component of each and every one of five units shall be within 5 % of that stated on the package [see 9.1 a)].

NOTE 1 The components used for the determinations specified in 3.3 and 4.2 may be used subsequently for other tests described in this International Standard.

## 5 Liquid-powder mixture intended for syringe usage

When determined by the methods given in tables 1 and 2, the setting properties, and the properties of the set cement, shall comply with the values given in tables 1 and 2.