



**International
Standard**

ISO 5833

**Implants for surgery — Acrylic resin
cements**

Implants chirurgicaux — Ciments à base de résine acrylique

**Third edition
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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This third edition cancels and replaces the second edition (ISO 5833:2002), which has been technically revised.

The main changes are as follows:

- the scope has been amended to specify that the requirements in this document do not apply to acrylic resin cements for other applications;
- ASTM F451-21 has been added as a normative reference;
- terms and definitions of ASTM F451 have been cited in [Clause 3](#);
- [subclause 5.4](#) on initiator agent concentration has been added, which includes a requirement for the measuring the concentration of the initiator agent;
- [Clauses 6](#) and [7](#) have been revised and a new [Clause 8](#) has been added which include the requirements for liquid-powder mixture intended for syringe usage, use in dough state, and dual usage (both syringe and dough state usage), respectively.
- a requirement to perform an extrusion viscosity test has been added to [6.2](#);
- a clarification for when to perform an intrusion test has been added to [7.2](#);
- a clarification for when to perform both an intrusion and extrusion test has been added to [8.2](#);
- [subclause 9.2](#) on monitoring leachable monomer from set and polymerized cement has been added to provide a requirement to measure leaching monomer from set and polymerized cement over time;
- a new [Clause 12](#) has been added on biocompatibility;
- the reporting sections in all Annexes have been revised;

— bibliographical references have been added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Implants for surgery — Acrylic resin cements

1 Scope

This document 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). This document 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.

All requirements in this document apply to, and all test methods are intended to be performed on, a sterile product.

The requirements in this document are not intended to apply to acrylic resin cements for other applications, such as stabilization of spinal fractures, fixation of bone screws, bone anchors or augments, etc., although the test methods described can be applicable.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASTM F451-21, *Standard specification for acrylic bone cement*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ASTM F451 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 unit of cement

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

Note 1 to entry: 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.

4 Liquid component

4.1 Appearance

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

4.2 Stability

The stability test shall be performed as described in [Annex A](#). The flow time of the samples of liquid component shall not increase by more than 10 %.

4.3 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 [10.1 b](#)].

5 Powder component

5.1 General

The powder component includes the polymer particles, initiator agents and, if applicable, the radio-opaque agent. In some cases, the radio-opaque agent is supplied separately.

5.2 Appearance

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

5.3 Accuracy of contents

When weighed to an accuracy of $\pm 0,1$ g, the mass of the powder component of each of five units shall be within 5 % of that stated on the package [see [10.1 b](#)].

The components used for the determinations specified in [4.3](#) and [5.3](#) may be used subsequently for other tests described in this document, with the condition that there is no loss of mass or volume for each cement component produced and all the requirements of [Clause 4](#) and [Clause 5](#) are met.

5.4 Initiator agent concentration

The concentration of the initiator agent shall be measured. If benzoyl peroxide is used as an initiator, the amount of dibenzoyl peroxide (BPO) in the powder portion can be determined using the protocol described in ASTM F451-21, Clause A.1, Clause A.2 or equivalent.

6 Liquid-powder mixture intended for syringe usage

6.1 Setting properties, test methods and requirements

When determined by the methods given in [Annexes B](#), [C](#), [E](#) and [F](#), the setting properties and the properties of the set and polymerized cement shall conform with the values given in [Tables 1](#) and [2](#).

Table 1 — Requirements and test methods for setting properties of liquid-powder mixtures

Mixture	Doughing time			Setting time		Maximum temperature		
	Average min	Maximum deviation from average min	Test method	Average min	Test method	Average °C	Maximum deviation from average °C	Test method
Syringe usage (see Clause 6)	—	—	—	6,5 to 15	Annex C	90 °C	±5	Annex C
Dough state usage (see Clause 7)	≤ 5	1,5	Annex B	3 to 15	Annex C	90 °C	±5	Annex C

Table 2 — Requirements and test methods for set and polymerized cement

Test	Requirement	Test method
Compressive strength	≥ 70 MPa	Annex E
Bending modulus	≥ 1 800 MPa	Annex F
Bending strength	≥ 50 MPa	Annex F

6.2 Extrusion

The manufacturer shall evaluate the viscosity profile of the cement during its curing process using the test method(s) described in ASTM F451-21, 7.9.1 (extrusion, capillary viscosity) or 7.9.2 (extrusion, rotational shear viscosity), or both.

7 Liquid-powder mixture intended for use in dough state

7.1 Setting properties, test methods and requirements

When determined by the methods given in [Annexes B, C, D, E](#) and [F](#), the setting properties and the properties of the set and polymerized cement shall conform with the values given in [Tables 1](#) and [2](#).

7.2 Intrusion

The intrusion test shall be performed as described in [Annex D](#). The average intrusion of at least one sample shall be not less than 2 mm.

8 Liquid-powder mixture intended for dual usage (both syringe and dough state usage)

8.1 Setting properties, test methods and requirements

When determined by the methods given in [Annexes B, C, D, E](#) and [F](#), the setting properties and the properties of the set and polymerized cement shall conform with the values given in [Tables 1](#) and [2](#).

8.2 Intrusion and extrusion

If the mixture is to be used as a dual usage cement, then both intrusion and extrusion tests shall be performed and shall conform to the requirements in [6.2](#) and [7.2](#).