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Interested committees:

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 5833

Implants for surgery — Acrylic resin cements

Implants chirurgicaux — Ciments à base de résine acrylique

ICS: 11.040.40

ISO/TC 150/SC 1

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2025-11-20

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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 documents 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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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 compared to the previous edition are as follows:

- normative reference updated to include to ASTM F451-21 *Standards Specification for Acrylic Bone Cement*;
- added reference to ASTM F451 regarding terms and definitions;
- added [subclause 5.4](#) Initiator Agent Concentration which includes a requirement for the measuring the concentration of the initiator agent;
- added a requirement to [clause 6](#) to perform an extrusion viscosity test;
- added a clarification to [subclause 7.1](#) added, for when to perform an intrusion test or both an intrusion and extrusion test;
- added [subclause 8.1](#) Monitoring Leachable Monomer from Cured Bone Cement to add a requirement to measure leaching monomer from cured bone cement over time.

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.

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). 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 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.

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

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 F451-21 and the following apply.

ISO and IEC maintain terminological 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

one package or vial of sterile premeasured powder component and one package 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 no mass and/or volume loss for each cement component is produced, and all the requirements of [clause 4](#) and [clause 5](#) are satisfied.

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, Annex A.1, Annex A.2 or equivalent.

6 Liquid-powder mixture intended for syringe usage

When determined by the methods given in [Table 1](#) and [Table 2](#), the setting properties and the properties of the set cement shall comply with the values given in [Table 1](#) and [Table 2](#) and the test shall be performed as described in the referenced annexes.

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

Mixture	Doughing time			Setting time		Maximum temperature		
	Average	Maximum deviation from average	Test method	Average	Test method	Average	Maximum deviation from average	Test method
	min	min		min		°C	°C	
Syringe usage (see clause 6)	—	—	—	6,5 to 15	Annex C	90 °C	±5	Annex C
Dough state usage (see 7.1)	≤ 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

Average compressive strength		Bending modulus		Bending strength	
	Test method		Test method		Test method
MPa		MPa		MPa	
≥ 70	Annex E	≥ 1 800	Annex F	≥ 50	Annex F

In addition, the manufacturer shall perform one or both extrusion viscosity test(s) as described in ASTM F451-21, 7.9.1 (capillary viscosity) and/or 7.9.2 (rotational shear viscosity) .

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 cement shall comply with the values given in [Tables 1](#) and [2](#).

If the mixture is to be utilized in the dough stage, use the intrusion test in [7.2](#). If the mixture is to be used as a dual usage cement, then both the extrusion test, as described in ASTM F451-21, 7.9.1 and/or 7.9.2, and the intrusion test, as described in [subclause 7.2](#), shall be performed.

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 Set and polymerized cement

[Table 2](#) presents the requirements and test methods for set and polymerized cement.

8.1 Monitoring Leachable Monomer from Cured Bone Cement

Leaching monomer from cured bone cement shall be measured and monitored in accordance with ASTM F451-21, A.5.

9 Packaging

9.1 Each component of the cement shall be packaged and sterilized separately using a suitable method. The liquid component shall be sterilized by ultrafiltration prior to being filled into an aseptic container. Each component shall be packaged in a double-layer sealed container. The components of a single unit of cement shall be further packaged in a container that shall contain the accompanying documentation as described in [10.2](#) and shall present the information as described in [10.1](#).

Each component of the cement shall be packaged and sterilized in a double-layer sealed container and then packaged in an outer container which shall contain the accompanying documentation.

9.2 In the case of cement being sold with two cement units per container, the requirements of [9.1](#) shall apply.

9.3 The materials of the package should not contaminate or permit contamination of the contents. The packaging should prevent damage to, or leakage of, the contents during transit and storage and should be designed so that it is easy to open and facilitates aseptic presentation of the contents.