INTERNATIONAL STANDARD

ISO 5833

Second edition
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Implants for surgery — Acrylic resin cements

Implants chirurgicaux — Ciments à base de résine acrylique

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO 5833:1992), which has been technically revised.

Annexes A, B, C, D, E and F form a normative part of this International 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 ± 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)].

4 Powder component

4.1 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.

4.2 Appearance

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

4.3 Accuracy of contents

When weighed to an accuracy of ± 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 9.1 b)].

The components used for the determinations specified in 3.3 and 4.3 may be used subsequently for other tests described in this International Standard, with the condition that no mass and/or volume loss for each cement component is produced, and all the requirements of clauses 3 and 4 are satisfied.

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.

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 5)	—	—	—	6,5 to 15	Annex C	90	± 5	Annex C
Dough state usage (see 6.1)	⩽ 5	1,5	Annex B	3 to 15	Annex C	90	± 5	Annex C

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

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

6 Liquid-powder mixture intended for use in dough state

6.1 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.

6.2 Intrusion

When determined as described in annex D, the average intrusion of at least one sample shall be not less than 2 mm.

7 Set and polymerized cement

Table 2 presents the requirements and test methods for set and polymerized cement.

8 Packaging

8.1 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 9.2 and shall present the information as described in 9.1.

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.

8.2 In the case of cement being sold with two cement units per container, the requirements of 8.1 shall apply.

8.3 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.

9 Labelling

9.1 Unit package

At least the following information shall appear on the unit package of each cement unit:

a) a reference to this International Standard (ISO 5833);

b) a description of the contents, including the mass of the powder component and the mass or volume of the liquid component, and the generic names of the constituents;

c) the name and address of the manufacturer, and the supplier if different from the manufacturer;

d) a warning that the package contains flammable liquid;

e) a statement that the contents are sterile and a warning against the use of an opened or damaged package;

f) an instruction to store the package at a temperature below 25 °C, and away from strong light;

g) the batch or lot numbers of the liquid and the powder component and the expiry date of the material.

NOTE Legal requirements for labelling may apply in some countries.

9.2 Accompanying documentation

At least the following information shall appear on the accompanying documentation (see clause 8):

a) instructions for handling the components and preparing the cement for use, including details of the equipment needed and an instruction to mix the entire contents of the cement component packages. The instructions shall emphasise the importance of minimizing the entrapment of air;

b) instructions and recommendations for using the cement, including necessary precautions, and drawing attention to the expiry date marked on the package;

c) a statement drawing attention to the toxic, hazardous and irritant properties associated with the handling and use of the components and the cement;

d) a statement that high ambient or component temperatures will decrease, and low ambient or component temperatures will increase, the doughing, working and setting times of the cement;

e) whether the cement is intended for use with a syringe or in the dough state;

f) the relative proportions of the powder and liquid components, expressed as a percent mass or volume fraction;

g) a warning against re-sterilization of either the powder or liquid components;

h) a statement that, once opened, any pack should be completely used or discarded and not retained for use on a later occasion.

NOTE It is helpful to provide a graphical representation of the effect of temperature on the length of the phases in cement curing, prepared from experimental data on the particular brand of cement.

Annex A
(normative)

Determination of stability of liquid component

A.1 Principle

The flow time (viscosity) of the liquid component is determined before and after accelerated ageing by heating, and the increase in flow time after heating is calculated. Two units of the liquid component are tested.

A.2 Apparatus

A.2.1 **Clean glass U-tube viscometer**.

A.2.2 **Timing device**, with an accuracy of $\pm$ 0,1 s.

A.2.3 **Means of heating test specimens**.

A.3 Test conditions

Condition the viscometer and the test specimens at (23 $\pm$ 1) °C for at least 1 h before beginning the test. Perform the viscosity measurements at (23 $\pm$ 1) °C.

A.4 Procedure

A.4.1 Fill the viscometer in the usual way with the liquid component.

A.4.2 Record the flow time taken for the meniscus to fall to the equilibrium level (time t_a).

A.4.3 Heat an aliquot of the liquid component at (60 $\pm$ 2) °C for (48 $\pm$ 2) h in the dark in a closed container, allow it to cool to (23 $\pm$ 1) °C and to remain at this temperature for at least 1 h.

A.4.4 Repeat A.4.1 and A.4.2 and record the flow time (time t_b).

A.4.5 Repeat A.4.1 to A.4.4 on a second unit of liquid component.

A.5 Calculation and expression of results

Calculate the percentage change Δt in flow time for each unit of liquid component using the expression:

$$\Delta t = \frac{t_b - t_a}{t_a} \times 100\ \%$$

A.6 Test report

The test report shall include at least the following information:

a) a reference to this International Standard (ISO 5833);

b) identity (including batch or lot number) of the liquid component;

c) flow times before and after heating;

d) percentage change in flow time for each unit of cement.

Annex B
(normative)

Determination of doughing time of liquid-powder mixture of cement intended for dough usage

B.1 Principle

The cement is mixed and the time recorded from the beginning of mixing until the mixture is able to separate cleanly from a gloved finger. Either two or four units of cement are tested.

B.2 Apparatus

B.2.1 **Timing device**, with an accuracy of ± 1 s.

B.2.2 **Unpowdered latex surgical gloves**.

B.2.3 **Equipment**, as recommended by the cement manufacturer, for mixing cement.

B.3 Test conditions

Condition the mixing equipment and the contents of the cement units at (23 ± 1) °C and at a relative humidity (RH) of not less than 40 % for at least 2 h before beginning the test. Perform the test at (23 ± 1) °C and a RH of not less than 40 %.

B.4 Procedure

B.4.1 Mix all the components of a single unit of cement following the manufacturer's instructions. Start the timing device when the liquid is first added to the powder.

B.4.2 After approximately 1 min, gently touch the surface of the mixture with a finger gloved with an unpowdered non-water-rinsed latex surgical glove, and observe if fibres form between the cement and the glove as the finger leaves the surface. Clean the glove of all adherent material.

B.4.3 Repeat the probing process at maximum intervals of 15 s, gently mixing the cement so as to expose a fresh surface for each probing, ensuring that testing is performed on a fresh surface that has not previously been probed. Record the time at which the gloved finger first separates cleanly from the cement as the doughing time of that mixture.

B.4.4 Repeat the process described in B.4.1 through B.4.3 for a second unit of cement.

B.4.5 If the two doughing times differ by more than 30 s, repeat B.4.1 to B.4.3 for a further two units of cement.

B.5 Calculation and expression of results

Calculate the average doughing time of the two or four determinations made. Round the result to the nearest 15 s and express this as the average doughing time.