
International Standard



5833/1

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Implants for surgery — Acrylic resin cements — Part 1 : Orthopaedic applications

Implants chirurgicaux — Ciments à base de résine acrylique — Partie 1 : Applications orthopédiques

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FOREWORD

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 5833/1 was developed by Technical Committee ISO/TC 150, *Implants for surgery*, and was circulated to the member bodies in November 1977.

It has been approved by the member bodies of the following countries :

Australia	Germany, F. R.	Switzerland
Belgium	India	Turkey
Brazil	Italy	United Kingdom
Canada	New Zealand	USA
Czechoslovakia	South Africa, Rep. of	USSR
France	Spain	

No member body expressed disapproval of the document.

Implants for surgery — Acrylic resin cements — Part 1 : Orthopaedic applications

1 SCOPE

This International Standard specifies composition, physical performance and packaging requirements for self-curing resins based on poly(methyl methacrylate), and known as "acrylic bone cements", primarily used for the fixation of internal orthopaedic endoprostheses.

This International Standard does not deal with the toxicity or biocompatibility aspects of the cements.

2 FIELD OF APPLICATION

This International Standard is intended to be used only for the purpose of maintaining the uniformity of the product. The results obtained from the tests prescribed herein may not be directly correlatable with the performance of the product when placed in the human body.

3 DEFINITIONS

3.1 unit pack : One package or vial of pre-weighed powder component and one package or vial of pre-measured liquid component, together with any packages of radiopaque additives where such additives are packaged separately.

3.2 doughing time : The time after commencement of mixing at which the mixture ceases to adhere to a standard probe (see 7.4).

3.3 setting time : The time after commencement of mixing at which the rate of increase of temperature due to exothermic reaction is maximum (see 7.6).

3.4 exothermic temperature : The maximum temperature of the mixture due to self-curing in a standard mould (see 7.5).

3.5 intrusion : The distance of flow of the mixture into a standard mould under load (see 7.7).

3.6 indentation : The penetration value in a one day old specimen derived from dial gauge readings on a Rockwell hardness tester (see 7.9).

3.7 recovery : The per cent change in penetration upon removal of the indentation load (see 7.9).

4 COMPOSITION

While a variety of co-polymers and co-monomers may be incorporated, the set cement shall contain poly(methyl methacrylate) as its main ingredient.

5 PHYSICAL REQUIREMENTS

5.1 Liquid component

5.1.1 Appearance

The liquid shall be clear and free of any particulate matter or sediment, when viewed against an illuminated screen (see 7.2.1).

5.1.2 Stability

The liquid shall show no turbidity or deposit when subjected to the procedure described in 7.3.

5.1.3 Sterility

The liquid shall be sterile.

5.2 Powder component

5.2.1 Appearance

The powder shall be pourable and free from extraneous materials such as dirt or lint (see 7.2.2).

5.2.2 Sterility

The powder shall be sterile.

5.3 Powder-liquid mixture

The properties of the powder-liquid mixture determined by the relevant method under clause 7 shall be in accordance with the values specified in table 1.

TABLE 1 — Properties of powder-liquid mixture

Doughing time	Setting time	Exothermic temperature	Intrusion
maximum	range	maximum	minimum
5,0 minutes	4 to 15 minutes	90 °C	2,0 mm

5.4 Cured polymer

The properties of the cured polymer determined by the relevant method under clause 7 shall conform to the values prescribed in table 2.

TABLE 2 — Properties of cured polymer

Compressive strength	Recovery	Indentation
minimum	minimum	maximum
70 MPa	60 %	0,2 mm

6 TEST SAMPLES

Nine unit packs of the cement shall be procured to provide sufficient material for all the tests prescribed in this International Standard.

7 METHODS OF TEST

7.1 Test conditions

Unless otherwise specified,

- a) all equipment, mixing surfaces and materials shall have been conditioned at a temperature of 23 ± 2 °C and 50 ± 10 % relative humidity; and
- b) tests shall be performed under these conditions.

7.2 Inspection

Visual inspection by the naked eye shall be used in determining compliance with the requirements specified in 5.1.1, 5.2.1, 7.3, 7.4, 10.1 and 10.2.

7.2.1 The liquid component shall comply with the requirements of 5.1, 9.1, 9.2, 10.1 and 10.2.

7.2.2 The powder component shall comply with the requirements of 5.2, 9.1, 9.2, 10.1 and 10.2.

7.3 Effect of storage at 60 °C on liquid component

A 1 ml specimen of liquid shall be taken from a package or vial of liquid which has been held for a period of 24 h in a covered vessel at a temperature of 60 ± 2 °C.

After the sample has been allowed to cool to 23 °C, it shall be poured into 20 ml of analytical grade methanol. No turbidity or white deposit shall be observed (see 7.2).

7.4 Doughing time

All the powder and liquid of a single unit pack shall be mixed together as directed by the manufacturer's instructions [see 10.2 b)]. A stopwatch shall be started at the commencement of mixing and all subsequent times shall be read from this stopwatch.

Approximately 1,5 min after the onset of mixing, the mixture shall be probed gently to a depth of approximately 10 mm with a clean glass rod of approximately 10 mm diameter and having a rounded probing end. The rod shall be wiped clean between determinations. As it leaves the surface, the rod shall be examined (see 7.2) for the formation of fibres between it and the surface of the mix. This process of probing shall be repeated from that time on, at 15 s intervals, until the rod separates cleanly without any material adhering. The time at which this is first observed is denoted as the doughing time. The mixture shall be mixed between determinations to expose fresh material for each probing.

7.4.1 Two separate determinations of the doughing time shall be made.

7.4.2 The two values shall agree within 30 s of each other, otherwise the test shall be repeated on a third unit. If the third determination does not agree within 30 s of one of the other determinations, the material shall have failed the requirements for doughing time.

7.4.3 The doughing time shall be deemed to be the average of all determinations reported to the nearest 15 s (see 5.3.1 and 10.2).

7.5 Exothermic temperature

Within 1 min after expiry of the doughing time, approximately 25 g of the dough made as described in 7.4 shall be gently packed into the plunger cavity of the mould as shown in figure 1. This mould shall be made of polytetrafluoroethylene (PTFE) or other suitable material and be equipped with a thermocouple (wire diameter approximately 0,5 mm) or similar device positioned with its junction in the centre of the mould at a height of 3,0 mm in the internal cavity. The plunger shall be immediately seated with a C-clamp or suitable press to produce the $6,0 \pm 0,1$ mm specimen height.

After the plunger has been seated, the excess material and the C-clamp or press shall be removed for the remainder of the procedure. The temperature shall be continuously recorded.