

Non-metallic materials for surgical implants —

Part 1: Specification for acrylic resin cement

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Healthcare Standards Policy Committee (HCC/-) to Technical Committee HCC/18, upon which the following bodies were represented:

- Association of British Healthcare Industries
- British Forging Industry Association
- British Industrial Ceramic Manufacturers' Association
- British Institute of Surgical Technologists
- British Investment Casting Trade Association
- British Medical Association
- British Orthopaedic Association
- British Steel Industry
- British Surgical Trades Association
- Department of Health
- Department of Trade and Industry (Laboratory of the Government Chemist)
- Royal College of Surgeons of England
- Royal Veterinary College
- Scottish Office
- Sterilised Suture Manufacturers' Association
- Surgical Dressings Manufacturers' Association

The following bodies were also represented in the drafting of the standard, through subcommittees and panels:

- Department of Trade and Industry (National Physical Laboratory)

This British Standard, having been prepared under the direction of the Healthcare Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 June 1993

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National foreword

This Part of BS 7253 has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with ISO 5833:1992 *Implants for surgery — Acrylic resin cements*, published by the International Organization for Standardization (ISO) and supersedes BS 7253-1:1990.

Requirements for acrylic bone cement were first published in BS 3531-7:1981. As a result of the development of so many disparate Parts of BS 3531 and because of the anticipated need to implement a number of published and forthcoming ISO standards that would have increased the diversity of BS 3531 still further, it was decided that BS 3531 should be restructured as five distinct standards which would enable the various aspects to be clearly differentiated. BS 3531 itself was limited to standards specific to implants for osteosynthesis and its title changed accordingly. Four new standards:

BS 7251, *Orthopaedic joint prostheses*.

BS 7252, *Metallic materials for surgical implants*.

BS 7253, *Non-metallic materials for surgical implants*.

BS 7254, *Orthopaedic implants*.

were published incorporating Parts of BS 3531 as well as new ISO standards.

The publication of BS 7253-1:1990 introduced editorial changes to reflect this restructuring but made no technical changes to the specification for acrylic bone cement first published as BS 3531-7:1981.

This revision of BS 7253-1 amends the title of the specification. The acrylic resin cement is still based on poly(methacrylic acid esters), known as bone cement. The specification now specifies two types of resin cement, intended for use with a syringe or in the dough state. Methods of test for determining the stability of the liquid component, the doughing time, the maximum temperature, the setting time and the intrusion of the liquid-powder mixture, as well as the compressive strength, bending modulus and bending strength of the cement are given in the annexes.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continuing surveillance, which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750.

Enquiries as to the availability of third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 15 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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 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.

6 Liquid-powder mixture intended for use in dough state

6.1 Setting properties

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.

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 cured cement

Table 2 sets out the requirements and test methods for set and cured cement.

8 Packaging

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.

The materials of the package should not contaminate or permit contamination of the contents. The packaging should prevent damage to, or leakage 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 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;
- the relative proportions of the powder and liquid components expressed as a mass or volume percent;
- the name and address of the manufacturer, and the supplier if different from the manufacturer;
- a statement that the contents are sterile, and a warning against the use of an opened or damaged package;
- a warning that the package contains flammable liquid;
- an instruction to store the package in the dark at below 25 °C;
- the batch or lot numbers of the liquid and the powder component and the expiry date of the material;
- the number and date of this International Standard (i.e. ISO 5833:1992).

NOTE 2 Legal requirements for labelling may apply in some countries.

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 max.	1,5	Annex B	3 to 15	Annex C	90	± 5	Annex C

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

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