BRITISH STANDARD

BS ISO 5833:2002

Implants for surgery — Acrylic resin cements

ICS 11.040.40

This British Standard reproduces verbatim ISO 5833:2002 and implements it as the UK national standard. It supersedes BS 7253-1:1993 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/18, Surgical implant materials, to Subcommittee CH/18/1, Non-metallic materials, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international publications referred to in this document may be found in the *BSI Catalogue* under the section entitled "International Standards Correspondence Index", or by using the "Search" facility of the *BSI Electronic Catalogue* or British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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

This British Standard, having been prepared under the direction of the Health and Environment Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 24 June 2002

Summary of pages

This document comprises a front cover, an inside front cover, the ISO title page, pages ii to iv, pages 1 to 22, an inside back cover and a back cover.

The BSI copyright date displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

ISBN 0 580 39219 8

Second edition
2002-05-01

Implants for surgery — Acrylic resin cements

Implants chirurgicaux — Ciments à base de résine acrylique

Reference number
ISO 5833:2002(E)

Contents

Annexes

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)].