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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 $\pm 0,1$ ml, the volume of the liquid component of each of five units shall be within 5 % of that stated on the package [see 9.1 b)].