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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0459-2025

Replacing YY 0459-2003

Implants for surgery - Acrylic resin cements

外科植入物 丙烯酸类树脂骨水泥

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. This document replaces YY 0459-2003 "Acrylic Resin Bone Cement for Surgical Implants". Compared with YY 0459-2003, In addition to structural adjustments and editorial changes, the main technical changes are as follows:

--- Changed the requirements for "precision of contents" (see 4.3,

3.3 of the.2003 edition);

--- Changed the "average value" of "maximum temperature" in Table 1 from "90" to "<=90" (see Table 1 in Chapter 6,.2003 Edition Table 1 in Chapter 5);

--- Changed the test steps of "Determination of stability of liquid components" (see A.4.2, A.4.4, A.4.2, A.4.4 of the.2003 edition);

--- Changed the test conditions for "Determination of dough time of bone cement powder-liquid mixture used in dough form" (see B.3,.2003 edition B.3);

--- Changed the test procedure of "Determination of dough time of bone cement powder-liquid mixture used in dough form" (see B.4.1,.2003 B.4.1 of the version);

--- Changed the test conditions of "Determination of maximum temperature and setting time of powder-liquid mixture" (see C.3, C.3 of the.2003 edition);

--- Changed the test steps of "Determination of compressive strength of bone cement" (see E.4.6, E.4.8, E.4.6, E.4.9 of the.2003 edition), deleted "The cylinder is kept at a constant temperature of (23 ± 1) °C" (see E.4.8 of the.2003 edition);

--- Changed the appropriate materials for preparing molds in the determination of flexural modulus and flexural strength of bone cement (see F.2.3,.2003 edition F.2.3);

--- Changed the test procedure of "Determination of flexural modulus and flexural strength of bone cement" (see F.4.4, F.4.4 of the.2003 edition). This document is modified from ISO 5833.2002 "Acrylic resin bone cements for surgical implants". This document has made the following structural adjustments compared to ISO 5833.2002.

--- Added "Normative references" (see Chapter 2), and the numbers of other clauses were adjusted accordingly. The technical differences between this document and ISO 5833-2.2002 and their reasons are as follows:

--- Changed the requirement of "Precision of contents" (see 4.3,

1 Scope

YY 0459 is the mandatory standard for acrylic bone cement, the polymethacrylate resin that fixes a joint prosthesis to bone and that surgeons mix in theatre minutes before it sets. It specifies the physical, mechanical, marking and packaging requirements for cured polymeric resin bone cements based mainly on polymethacrylate, covering both radiopaque and non-radiopaque types. Bone cement is unusual among implant materials in that the hospital makes the final product: the working time, the setting behaviour, the exotherm and the mechanical properties that result all depend on a mixing step the manufacturer does not perform. The YY prefix without /T makes compliance compulsory, and the 2025 edition takes effect on 1 March 2028. For a manufacturer or an importer of bone cement for the Chinese market, this is the governing document.

This document specifies the materials for radiopaque and radiolucent curing polymeric resin bone cements, primarily based on polymethacrylates. The two types of bone cement are available in syringes or in dough form and are mainly used in artificial joint replacement. Internal fixation of prostheses during surgery. Bone cement is supplied in sets of sterile powder and sterile liquid in measured quantities, suitable for mixing at the time of implantation. This document does not address the risks to patients or users of bone cement when using bone cement. All requirements and all tests apply only to sterile products.

Note. For other bone cements not used for artificial joint replacement, refer to this document.

2 Normative references

This document has no normative references.

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Unit of cement One package or bottle of sterile powder and one package or bottle of sterile liquid. NOTE. For bone cements that are supplied with a radiopaque agent alone, the individual sets of bone cement also contain a packet or bottle of measured radiopaque powder component.

4 Liquid components

4.1 Appearance When examined with normal or corrected vision, the fluid should be free of particles and other impurities.

4.2 Stability When tested according to the method described in Appendix A, the increase in the flow time of the liquid sample should not exceed 10%.

4.3 Precision of contents When the measurement accuracy is ±

0.1 mL or ±

0.1 g, the volume or mass of each liquid component in the 5 sets of bone cement should not exceed the nominal value of the package. ±5% of the value [see 10.1b)].

5 Powder components

5.1 Overview The powder components include polymer particles, initiators, and, in the case of radiopaque bone cement, radiopaque agents. In the following cases, the radiopaque agent is provided separately.