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International

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Implants for surgery — Acrylic resin cements

Implants chirurgicaux — Ciments à base de résine acrylique

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This third edition cancels and replaces the second edition (ISO 5833:2002), which has been technically revised.

The main changes are as follows:

— the scope has been amended to specify that the requirements in this document do not apply to acrylic resin cements for other applications;

— ASTM F451-21 has been added as a normative reference;

— terms and definitions of ASTM F451 have been cited in Clause 3;

— subclause 5.4 on initiator agent concentration has been added, which includes a requirement for the measuring the concentration of the initiator agent;

— Clauses 6 and 7 have been revised and a new Clause 8 has been added which include the requirements for liquid-powder mixture intended for syringe usage, use in dough state, and dual usage (both syringe and dough state usage), respectively.

— a requirement to perform an extrusion viscosity test has been added to 6.2;

— a clarification for when to perform an intrusion test has been added to 7.2;

— a clarification for when to perform both an intrusion and extrusion test has been added to 8.2;

— subclause 9.2 on monitoring leachable monomer from set and polymerized cement has been added to provide a requirement to measure leaching monomer from set and polymerized cement over time;

— a new Clause 12 has been added on biocompatibility;

— the reporting sections in all Annexes have been revised;

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