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Implants for surgery — Hydroxyapatite —

Part 3: Chemical analysis and characterization of crystallinity and phase purity

Implants chirurgicaux — Hydroxyapatite —

Partie 3: Analyse chimique et caractérisation de la cristallinité et de la pureté de phase

Reference number
ISO 13779-3:2008(E)

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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 13779-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

ISO 13779 consists of the following parts, under the general title *Implants for surgery — Hydroxyapatite*:

— *Part 1: Ceramic hydroxyapatite*

— *Part 2: Coatings of hydroxyapatite*

— *Part 3: Chemical analysis and characterization of crystallinity and phase purity*

— *Part 4: Determination of coating adhesion strength*

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Introduction

No known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body. However, long term clinical experience of the use of the material referred to in this part of ISO 13779 has shown that an applicable level of biological response can be expected, if the material is used in appropriate applications.

The biological response to coating of hydroxyapatite ceramic has been demonstrated by a history of its clinical use and by laboratory studies.

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Implants for surgery — Hydroxyapatite —

Part 3: Chemical analysis and characterization of crystallinity and phase purity

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1 Scope

This part of ISO 13779 specifies methods of test for the chemical analysis and assessment of crystallinity and phase composition of hydroxyapatite-based materials such as coatings and sintered products.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 565, *Test sieves — Metal wire cloth, perforated metal plate and electroformed sheet — Nominal sizes of openings*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 10993-14, *Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics*

ISO 13779-2, *Implants for surgery — Hydroxyapatite — Part 2: Coatings of hydroxyapatite*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

Sheets JCPDS 09-0169; JCPDS 9-348; JCPDS 9-432; JCPDS 72-1243; JCPDS 25-1137; JCPDS 70-1379; JCPDS 4-0777; JCPDS 82-1690 *Elements of X-ray Diffraction*, B. D. CULLINITY, 2nd ed., Addison-Wesley, Reading, MA, 1978 (JCPDS = Joint Committee on Powder Diffraction Standards)

3 Terms, definitions and symbols

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1.1
calibration curve
calculating plot translating the integrated intensity measured on the X-ray diffraction pattern into the foreign phases content or calcium:phosphorus (Ca:P) ratio

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