INTERNATIONAL STANDARD

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Implants for surgery — Hydroxyapatite —

Part 1: Ceramic hydroxyapatite

Implants chirurgicaux — Hydroxyapatite —

Partie 1: Céramique à base d'hydroxyapatite

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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 part of ISO 13779 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 13779-1 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*

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 acceptable level of biological response can be expected, if the material is used in appropriate applications.

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

Implants for surgery — Hydroxyapatite —

Part 1: Ceramic hydroxyapatite

1 Scope

This part of ISO 13779 specifies requirements for ceramic hydroxyapatite intended for use as surgical implants.

This part of ISO 13779 does not apply to hydroxyapatite coatings, non-ceramic hydroxyapatite, hydroxyapatite powder, glass ceramics, α- and β-tricalcium orthophosphate or other forms of calcium phosphate.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 13779. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 13779 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 10993-17:—[1)], *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances using health-based risk assessment.*

ISO 13779-3:—[1)], *Implants for surgery — Hydroxyapatite — Part 3: Chemical analysis and characterization of crystallinity and phase purity.*

3 Terms and definitions

For the purposes of this part of ISO 13779, the following terms and definitions apply.

3.1
ceramic hydroxyapatite
hydroxyapatite which has been sintered into a coherent crystalline mass by subjecting it to conditions at which the crystals in the powder fuse together

3.2
hydroxyapatite
chemical compound with a crystallographic structure characterized by the powder diffraction file PDF 9-432 of the International Committee for Diffraction Data ICDD, USA

NOTE The chemical formula is $Ca_5(OH)(PO_4)_3$.

1) To be published.

3.3
sintering
process for production of ceramics in which the application of heat causes a significant reduction of particle surface area and bulk volume to achieve densification and consequent increase in mechanical properties

4 Requirements

4.1 Chemical analysis

The content of calcium and phosphorus of the hydroxyapatite ceramic shall be determined in accordance with ISO 13779-3. The calcium to phosphorus ratio, Ca/P, shall have a value of $1{,}65 \leqslant \text{Ca/P} \leqslant 1{,}82$ for the atomic ratio. This shall be determined as specified in ISO 13779-3.

4.2 Trace elements

The limits of specific trace elements for ceramic hydroxyapatite are given in Table 1.

The maximum allowable limit for metals having adverse biological reactions is a total of 50 mg/kg. The trace element levels shall be determined as specified in ISO 13779-3.

Assessment of the risk posed by other chemical impurities shall be carried out in accordance with ISO 10993-17.

Table 1 — Limits of specific trace elements

Element	Maximum limit mg/kg
Arsenic	3
Cadmium	5
Mercury	5
Lead	30

4.3 Crystalline content

The hydroxyapatite phase shall be not less than 95 % crystalline. The total maximum allowable level of other crystalline phases shall be 5 %, with the balance being amorphous.

The quantitative determination of the content of the hydroxyapatite phase and of other crystalline phases shall be determined in accordance with ISO 13779-3.

4.4 Mechanical properties — Compression strength

The compression strength of sintered ceramic hydroxyapatite shall be not less than 1,5 MPa and shall exhibit no anisotropy.

The compression strength shall be determined by applying an axial load to a cylindrical test specimen of height h, and diameter d, with a ratio of dimensions h/d between 1,5 and 2,0.

The compression strength shall be calculated by determining the mean value of the load force recorded at the moment of initial cracking.

Bibliography

[1] ISO 5961:1994, *Water quality — Determination of cadmium by atomic absorption spectrometry*.

[2] ISO 8288:1986, *Water quality — Determination of cobalt, nickel, copper, zinc, cadmium and lead — Flame atomic absorption spectrometric methods.*

[3] NF S 94-065, *Materials for surgical implants — Determination of arsenic, mercury, cadmium and lead on coating based on phosphate of calcium*.

[4] NF S 94-066, *Materials for surgical implants — Quantitative determination of the Ca/P ratio of calcium phosphate.*

[5] NF S 94-067, *Materials for surgical implants — Qualitative and quantitative determination of the foreign phases present in calcium phosphate-based powders, deposits and ceramics.*

[6] NF S 94-068, *Materials for surgical implants— Determination of the crystallinity and apparent size of the apatite crystallites of hydroxyapatite-based powders, deposits and ceramics.*

[7] ASTM F 11851988, *Standard specification for composition of ceramic hydroxylapatite for surgical implants.*

[8] ICDD cards 9-432, 9-348, 9-169, 25-1137, 37-1497, 9-80, 9-77, 14-1475, 5-586 X-ray diffraction standards for hydroxyapatite, α-tricalcium orthophosphate, β-tricalcium orthophosphate, tetracalcium phosphate, calciumoxide, monetite, brushite, aragonite, calcite.

[9] Hideki AOKI, *Medical Applications of Hydroxyapatite*, Ishiyaku EuroAmerica, Tokyo, 1994.

[10] H. DENISSEN, Dental Root Implants of Apatite Ceramics Doctoral Thesis, Vrije Universiteit Amsterdam, 1979.

[11] J. H. QUINN and J. N. KENT, Alveolar Ridge Maintenance with Solid Non-porous Hydroxyapatite Root Implants. *Oral Surg.*, **58**, pp. 511-516, 1984.

[12] K. DE GROOT, *Bioceramics of Calcium Phosphate,* CRC Press, Boca Raton, USA, 1983.

[13] H. OONISHI *et al.*, Clinical Significance of Chemical Bonds between Bioactive Ceramics and Bone in Orthopaedic Surgery, in: *Bioceramics 2*, G Heimke (ed.), Deutsche Keramische Gesellschaft.

[14] R. Z. LEGEROS and J. P. LEGEROS, Dense Hydroxyapaptite, in *An Introduction to Bioceramics*, L. Hench and J. Wilson (eds.), World Scientific, 1993, pp. 199-221.

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