
**Implants for surgery — Hydroxyapatite —
Part 2:
Coatings of hydroxyapatite**

Implants chirurgicaux — Hydroxyapatite —

Partie 2: Revêtements à base d'hydroxyapatite



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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
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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 13779-2 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 coatings of hydroxyapatite ceramic has been demonstrated by a history of clinical use and by laboratory studies. See Bibliography.

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Implants for surgery — Hydroxyapatite —

Part 2: Coatings of hydroxyapatite

1 Scope

This part of ISO 13779 specifies requirements for ceramic hydroxyapatite coatings applied to metallic or non-metallic surgical implants.

This part of ISO 13779 does not apply to coatings made from glasses, glass ceramics, α - and β -calcium orthophosphate or other forms of calcium phosphate, nor does it apply to coatings in which the hydroxyapatite is present in a powder form.

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 permissible limits and process residues using health-based risk assessment.*

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

ISO 13779-4: —¹⁾ *Implants for surgery — Hydroxyapatite — Part 4: Determination of coating adhesion strength.*

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 formed into a coherent crystalline mass by subjecting it to conditions at which the crystals in the powder fuse together

1) To be published.

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 $\text{Ca}_5(\text{OH})(\text{PO}_4)_3$.

3.3**coating**

hydroxyapatite which has been deposited onto the surface of a metallic or non-metallic substrate, either by means of a thermal spray process which produces a ceramic-type coating, or by means of a solution based technique which may deposit hydroxyapatite directly or may require thermal or other treatment to convert it into a crystalline form

4 Requirements**4.1 Chemical analysis**

The content of calcium and phosphorus of the hydroxyapatite ceramic coating shall be determined in accordance with ISO 13779-3. The calcium to phosphorus ratio, Ca/P, shall have a value in the range of 1,67 to 1,76 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

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

4.3 Crystalline content

The content of crystalline hydroxyapatite shall be not less than 45 %. The maximum allowable level of other crystalline phases shall be 5 %, with the balance being amorphous.

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

4.4 Adhesion to substrate

The adhesion to the substrate material shall be determined in accordance with the method described in ISO 13779-4 and shall have a value for adhesion strength of not less than 15 MPa.

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