INTERNATIONAL STANDARD

ISO 13779-2

Second edition
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Implants for surgery — Hydroxyapatite —

Part 2: Coatings of hydroxyapatite

Implants chirurgicaux — Hydroxyapatite —

Partie 2: Revêtements 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 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 13779-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This second edition cancels and replaces the first edition (ISO 13779-2:2000), which has been technically revised.

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 be completely free of adverse reactions in the human body. However, long-term clinical experience of the use of the material referred to in 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 coatings has been demonstrated by a history of clinical use and by laboratory studies. See Bibliography.

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 cover coatings made from glasses, glass ceramics, alpha- and beta-calcium orthophosphate or other forms of calcium phosphate, nor does it cover coatings in which the hydroxyapatite is present in a powder form.

This part of ISO 13779 does not apply to nanoparticle-type materials.

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 10993-17, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances*

ISO 13779-1, *Implants for surgery — Hydroxyapatite — Part 1: Ceramic hydroxyapatite*

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13779-1 and the following apply.

3.1
coating
hydroxyapatite that has been deposited on to 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 can deposit hydroxyapatite directly or might require thermal or other treatment to convert it into a crystalline form

4 Coating preparation

The coating to be tested shall be representative of the final product i.e. produced in the same way as the coating for the implant and subjected to any other final process like cleaning and sterilization.

5 Requirements

5.1 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.

5.2 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 shall be 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 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

5.3 Crystalline phase compositions

Allowed % mass fraction of crystalline phases:

— hydroxyapatite shall be 50 % mass fraction or greater;

— α-tricalcium phosphate (α-TCP), β-tricalcium phosphate (β-TCP), tetracalcium phosphate (TTCP) and calcium oxide (CaO) shall each be equal to or less than 5 % mass fraction.

5.4 Crystallinity value

The hydroxyapatite phase (50 % mass fraction or higher) shall have a crystallinity value not less than 45 % of the 100 % crystalline hydroxyapatite standard value as determined by ISO 13779-3.

5.5 Adhesion to substrate

The adhesion to the substrate shall be determined in accordance with the method described in ISO 13779-4.

At least 6 specimens shall be tested.

The mean coating adhesion strength shall be $\geqslant$ 15 MPa unless a lower value can be justified based on the intended application.

NOTE In some applications, a higher value can be recommended.

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[4] ASTM F 1609-03, *Standard Specification for Calcium Phosphate Coatings for Implantable Materials*

[5] ASTM F 1185-03, *Standard Specification for Composition of Hydroxyapatite for Surgical Implants*

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