INTERNATIONAL STANDARD

**ISO 13779-1**

Second edition
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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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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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 13779-1 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 13779-1:2000), 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 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 applies to hydroxyapatite blocks.

It does not apply to hydroxyapatite coatings, hydroxyapatite powder or nanoparticle-type and calcium phosphate ceramics which are not mainly composed of crystalline hydroxyapatite.

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

## 3 Terms and definitions

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

**3.1**
**ceramic hydroxyapatite**
hydroxyapatite that has been sintered into a coherent crystalline mass and which contains more than 50 % mass fraction of crystalline hydroxyapatite

**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 $Ca_5(OH)(PO_4)_3$.

**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 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<br>mg/kg |
|---|---|
| Arsenic | 3 |
| Cadmium | 5 |
| Mercury | 5 |
| Lead | 30 |

## 4.3 Crystalline phase compositions

Allowed % mass fraction of crystalline phases:

— hydroxyapatite shall be 50 % mass fraction or greater;

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

## 4.4 Crystallinity value

The hydroxyapatite phase (50 % mass fraction or higher) shall have a crystallinity value not less than 95 % of the 100 % crystalline hydroxyapatite standard value as determined by ISO 13779-3.

## 4.5 Mechanical properties — Compression strength

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 first significant deviation from linearity in the load-deflection diagram.

NOTE If the implant is designed for load bearing applications, the manufacturer should demonstrate that the mechanical strength of the implants is adapted to local stresses.