INTERNATIONAL STANDARD

ISO 13779-3

Second edition
2018-12

Implants for surgery — Hydroxyapatite —

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

Implants chirurgicaux — Hydroxyapatite —

Partie 3: Analyse chimique et caractérisation du rapport de cristallinité et de la puréte de phase

Reference number
ISO 13779-3:2018(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document 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 13779-3:2008), which has been technically revised.

A list of all parts in the ISO 13779 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 hydroxyapatite has shown that an applicable level of biological response can be expected, if the material is used in appropriate applications.

Biocompatibility and resorption rate of hydroxyapatite material for surgical application may depend of the presence of trace elements, foreign crystalline phases and crystallinity ratio. Amorphous calcium phosphate, tetracalcium phosphate, α-tricalcium phosphate and β-tricalcium phosphate have demonstrated to have a higher solubility and may resorb more rapidly than hydroxyapatite in the body. CaO and heavy metals may impair the biocompatibility of the material. As a consequence, it is important to assess the composition of the material.

In this field, the assessment of the different crystalline and amorphous phase components has been under continuing development (of both equipment and processing software). In this document a new method for measuring the crystallinity ratio of hydroxyapatite is introduced and the Rietveld method is introduced as an alternative method for measuring the foreign phase content.

Implants for surgery — Hydroxyapatite —

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

1 Scope

This document specifies methods of test for the chemical analysis, assessment of crystallinity ratio and phase composition of hydroxyapatite-based materials such as powders, coating or bulk products.

NOTE These tests are intended to describe properties of the material and to communicate these between organizations. These tests are not written with the objective of replacing a company's internal operational and assessment tests although they could be used as such.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 3310-1, *Test sieves — Technical requirements and testing — Part 1: Test sieves of metal wire cloth*

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

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
calibration curve
calculating plot translating the ratio of integrated intensity of foreign phases, measured on the X-ray diffraction pattern into the mass fraction of foreign phases compared to crystalline hydroxyapatite

3.2
detection limit
DL
lowest quantity of the foreign phase or trace element that can be distinguished from the absence of that foreign phase or trace element

Note 1 to entry: Requirements and procedure for estimating the detection limit of foreign phases is established in 5.6.3.