INTERNATIONAL STANDARD

ISO 13779-4

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Implants for surgery — Hydroxyapatite —

Part 4: Determination of coating adhesion strength

Implants chirurgicaux — Hydroxyapatite —

Partie 4: Détermination de la résistance à l'adhésion du revêtement

Reference number
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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.

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 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 13779-4 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 cristallinity and phase purity*

— *Part 4: Determination of coating adhesion strength*

Future parts will deal with other relevant aspects of implant material based on hydroxyapatite.

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 the Bibliography for further information.

Implants for surgery — Hydroxyapatite —

Part 4:
Determination of coating adhesion strength

1 Scope

This part of ISO 13779 specifies test methods for measurement of the adhesion strength of hydroxyapatite coatings intended for use on components of surgical implants.

2 Normative reference

The following normative document contains 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 edition of the normative document 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 7500-1:1999, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Verification and calibration of the force-measuring system*

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

[ISO 13779-1]

3.2
coating
distinct layer of material deposited onto the surface of a metallic or non-metallic substrate by either a thermal, vapour or aqueous route

3.3
hydroxyapatite
chemical compound with a crystallographic structure characterized by the powder diffraction file PDF 9-432 of the International Committee for Diffraction Data ICDD, Newton Square, Pennsylvania, USA

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

[ISO 13779-1]