INTERNATIONAL STANDARD

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Implants for surgery — Calcium phosphates —

Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes

Implants chirurgicaux — Phosphates de calcium —

Partie 3: Substituts osseux à base d'hydroxyapatite et de phosphate tricalcique bêta

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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 13175-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

ISO 13175 consists of the following parts, under the general title *Implants for surgery — Calcium phosphates*:

— *Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes*

Introduction

Hydroxyapatite and β-tricalcium phosphate synthetic bone substitutes are now considered as an adequate alternative to autografts and allografts. Indeed, the synthetic origin of these devices guarantees that no transmittable disease will contaminate the patient. Moreover, hydroxyapatite and β-tricalcium phosphate have been shown to be osteoconductive which means that they will promote bone healing at the surface of the material if implanted in a bone site (see References [6] and [7]). Biocompatibility of hydroxyapatite and β-tricalcium phosphate is demonstrated by extensive literature (see Reference [8]).

The devices referred to in this part of ISO 13175 are of three types: synthetic monophasic hydroxyapatite or β-tricalcium phosphate bone substitutes and biphasic hydroxyapatite/β-tricalcium phosphate bone substitutes. The hydroxyapatite/β-tricalcium phosphate ratio influence the dissolution rate of the material: the higher the β-tricalcium phosphate content, the higher the dissolution rate (see References [9] to [11]).

The healing process into the bone substitutes is not only related to the material osteoconductive potential, it is also related to the porosity structure (see References [12] to [16]). It is necessary that macroporosities are large enough and interconnected for bone ingrowth to take place into the whole volume of the implant. Porosities have also an influence on the resorption rate of the ceramic: the higher the number of microporosities, the higher the dissolution rate (see Reference [14]).

As bone substitutes are not intended for bearing heavy loads, their mechanical properties are not essential. However, most of the time blocks have to be reshaped by the surgeon to fit the shape of the bone cavity. The bone substitute shall have sufficient mechanical properties to be machined.

Implants for surgery — Calcium phosphates —

Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes

1 Scope

This part of ISO 13175 specifies requirements for monophasic hydroxyapatite bone substitutes, monophasic β-tricalcium phosphate bone substitutes and biphasic hydroxyapatite/β-tricalcium phosphate bone substitutes in the form of blocks or granules.

This part of ISO 13175 is not applicable to cell-seeded bone void fillers, calcium phosphate cements or bone void fillers containing materials other than hydroxyapatite and β-tricalcium phosphate.

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 2591-1, *Test sieving — Part 1: Methods using test sieves of woven wire cloth and perforated metal plate*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 13320, *Particle size analysis — Laser diffraction methods*[1)]

ISO 13383-1, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Microstructural characterization — Part 1: Determination of grain size and size distribution*[2)]

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

ISO 15901-1, *Pore size distribution and porosity of solid materials by mercury porosimetry and gas adsorption — Part 1: Mercury porosimetry*

ISO 80000-1, *Quantities and units — Part 1: General*

3 Terms, definitions and symbols

3.1 Terms and definitions

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

1) Replaces ISO 13320-1.

2) To be published.