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Implants for surgery — Calcium phosphates

Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes

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National foreword

This British Standard is the UK implementation of ISO 13175-3:2012.

The UK participation in its preparation was entrusted to Technical Committee CH/150/1, Materials for surgical implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Foreword

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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*

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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.

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