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Implants for surgery — In vitro evaluation for apatite-forming ability of implant materials

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National foreword

This British Standard is the UK implementation of ISO 23317:2012. It supersedes BS ISO 23317:2007 which is withdrawn.

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.

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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.

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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 23317 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 23317:2007), which has been technically revised.

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Introduction

It has been revealed that materials of various kinds bond to living bone through a layer of apatite. It has been shown that this apatite layer can be reproduced on their surfaces in an acellular and protein-free simulated body fluid (SBF) with ion concentrations nearly equal to those of human blood plasma, and that apatite thus formed is similar to the bone mineral in its composition and structure.

This evaluation of apatite-forming ability on implant material in SBF is useful for evaluating its *in vivo* bone-bonding ability preliminary to animal experiments. When a bioactive material is implanted in a living body, a thin layer rich in Ca and P forms on its surface. The material then connects to the living tissue through this apatite layer without a distinct boundary. It has been shown that this apatite layer can be reproduced on the surfaces of materials in SBF as well, and that apatite thus formed is similar to bone mineral in its composition and structure. As bioactivity increases, apatite forms on the material surface in a shorter time in proportion to this increase. The formation of apatite layers can be detected by thin film X-ray diffraction spectrometry and/or scanning electron microscopy.

The apatite formed in the SBF is, however, similar to bone apatite in the following ways.

— Ca-deficient type apatite.

— Lower Ca/P atomic ratio than stoichiometric apatite.

— Containing some impurities such as Mg^{2+}, Na^{+}, Cl^{-}, HCO_3^{-}.

— Low crystallinity.

NOTE 1 The material which forms apatite on its surface *in vivo* can bond to living bone, since this apatite is biologically active. Their *in vivo* apatite deposition can be reproduced on their surfaces even *in vitro* in SBF. For example, *in vivo* calcification on surfaces of Bioglass®[1)], $CaO\text{-}SiO_2$ glasses, $Na_2O\text{-}CaO\text{-}SiO_2$ glasses, Cerabone®[1] A-W, Ceravital®[1]-type glass-ceramic, sintered hydroxyapatite and alkali-heat-treated titanium metal, are correlated with *in vitro* calcification in SBF. However, this does not exclude the possibility that materials, which do not form apatite on their surfaces *in vivo*, bond to living bone. For example, it is reported that such resorbable materials as beta-tricalcium phosphate [$Ca_3(PO_4)_2$] and calcium carbonate bond to living bone without forming an apatite layer on their surfaces.

NOTE 2 It has been reported that glasses with different compositions in the system $Na_2O\text{-}CaO\text{-}SiO_2$ show a correlation between bone-forming ability of materials implanted into a bone defect of a rabbit and apatite-forming ability on its surface in SBF.

1) Trade names of the products are examples of suitable products available commercially. This information is given for the convenience of the users of this document and does not constitute an endorsement by ISO of these products.

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