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

*Implants chirurgicaux — Évaluation in vitro de la capacité de
formation d'apatite des matériaux d'implants*

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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.

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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This third edition cancels and replaces the second edition (ISO 23317:2012), which has been editorially revised.

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 points.

- 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-SiO₂ glasses, Na₂O-CaO-SiO₂ glasses, Cerabone®²⁾ A-W, Ceravital®³⁾ -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 (Ca₃(PO₄)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 Na₂O-CaO-SiO₂ 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.

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

1 Scope

This International Standard specifies a method for detecting apatite formed on a surface of a material in simulated body fluid (SBF). It is applicable to implant surfaces intended to come into direct bone contact.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 14630, *Non-active surgical implants — General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14630 and the following apply.

3.1

apatite

group of calcium-phosphates including bone mineral and the main inorganic constituent of bones and teeth similar to hydroxyapatite, which has the composition $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$

Note 1 to entry: Bone mineral also contains ions such as CO_3^{2-} , F^- , Na^+ and Mg^{2+} .

3.2

apatite-forming ability

capability to develop apatite on the surface

3.3

bioactivity

property that elicits a specific biological response at the interface of the material, which results in the formation of a bond between tissue and material

3.4

induction period

time to detect apatite formation on a surface of a specimen after soaking the specimen in simulated body fluid

3.5

simulated body fluid

SBF

inorganic solution having a similar composition to human blood plasma without organic components

3.6

standard glass for evaluating apatite-forming ability

class of standard glasses with certain chemical compositions as shown in [Annex B](#) showing given apatite-forming abilities in SBF and when implanted in an animal body