INTERNATIONAL STANDARD

**ISO 6474-1**

Second edition
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# Implants for surgery — Ceramic materials —

## Part 1: Ceramic materials based on high purity alumina

*Implants chirurgicaux — Matériaux céramiques —*

*Partie 1: Matériaux céramiques à base d'alumine de haute pureté*



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# Foreword

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, SC 1, *Materials*.



This second edition cancels and replaces the first edition (ISO 6474-1:2010), which has been technically revised in Clause 6.

A list of all parts in the ISO 6474 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

# Introduction

No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long-term clinical experience of use of the material referred to in the ISO 6474 series has shown that an acceptable level of biological response can be expected, when the material is used in appropriate applications.

# Implants for surgery — Ceramic materials —

# Part 1:
# Ceramic materials based on high purity alumina

## 1 Scope

This document specifies the characteristics of, and corresponding test methods for bio-stable ceramic bone substitute material based on high purity alumina for use as bone spacers, bone replacements and components of orthopaedic joint prostheses.

This document does not cover biocompatibility (see ISO 10993-1). It is the responsibility of the manufacturer to evaluate the biocompatibility of ceramic materials which are produced within the framework of this document.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 12677, *Chemical analysis of refractory products by X-ray fluorescence (XRF) — Fused cast-bead method*

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



ISO 14704, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for flexural strength of monolithic ceramics at room temperature*

ISO 14705, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for hardness of monolithic ceramics at room temperature*

ISO 15732, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for fracture toughness of monolithic ceramics at room temperature by single edge precracked beam (SEPB) method*

ISO 16428, *Implants for surgery — Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices*

ISO 17561, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for elastic moduli of monolithic ceramics at room temperature by sonic resonance*

ISO 18754, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Determination of density and apparent porosity*

ISO 18756, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Determination of fracture toughness of monolithic ceramics at room temperature by the surface crack in flexure (SCF) method*

ISO 20501, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Weibull statistics for strength data*

ISO 22214, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for cyclic bending fatigue of monolithic ceramics at room temperature*

ISO 23146, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test methods for fracture toughness of monolithic ceramics — Single-edge V-notch beam (SEVNB) method*

EN 623-2, *Advanced technical ceramics — Monolithic ceramics — General and textural properties — Part 2: Determination of density and porosity*

EN 623-3, *Advanced technical ceramics — Monolithic ceramics — General and textural properties — Part 3: Determination of grain size and size distribution (characterized by the linear intercept method)*

EN 725-1, *Advanced technical ceramics — Methods of test for ceramic powders — Part 1: Determination of impurities in alumina*

EN 843-1, *Advanced technical ceramics — Mechanical properties of monolithic ceramics at room temperature — Part 1: Determination of flexural strength*

EN 843-2, *Advanced technical ceramics — Mechanical properties of monolithic ceramics at room temperature — Part 2: Determination of Young's modulus, shear modulus and Poisson's ratio*

EN 843-4, *Advanced technical ceramics — Mechanical properties of monolithic ceramics at room temperature — Part 4: Vickers, Knoop and Rockwell superficial hardness*

EN 843-5, *Advanced technical ceramics — Mechanical properties of monolithic ceramics at room temperature — Part 5: Statistical analysis*

CEN/TS 14425-5, *Advanced technical ceramics — Test methods for determination of fracture toughness of monolithic ceramics — Part 5: Single-edge vee-notch beam (SEVNB) method*

ASTM C1161, *Standard Test Method for Flexural Strength of Advanced Ceramics at Ambient Temperature*

ASTM C1198, *Standard Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Sonic Resonance*



ASTM C1239, *Standard Practice for Reporting Uniaxial Strength Data and Estimating Weibull Distribution Parameters for Advanced Ceramics*



ASTM C1259, *Standard Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Impulse Excitation of Vibration*

ASTM C1327, *Standard Test Method for Vickers Indentation Hardness of Advanced Ceramics*

ASTM C1331, *Standard Test Method for Measuring Ultrasonic Velocity in Advanced Ceramics with Broadband Pulse-Echo Cross-Correlation Method*

ASTM C1421, *Standard Test Methods for Determination of Fracture Toughness of Advanced Ceramics at Ambient Temperature*

ASTM C1499, *Standard Test Method for Monotonic Equibiaxial Flexural Strength of Advanced Ceramics at Ambient Temperature*

ASTM E112, *Standard Test Methods for Determining Average Grain Size*

## 3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

# 4 Classification

## 4.1 Material types

The material shall be classified as either type A or type B.

Ceramic materials of type A are intended for implants for high load applications (e.g. bearing surfaces of joint replacements).

Type B is intended for implants for low load applications (e.g. maxillofacial and middle-ear implants).

## 4.2 Test categories

### 4.2.1 General

The required tests shall be distinguished in category 1 and category 2.

The tests in 6.6, 6.8 and 6.9 shall only be applied for type A materials.

### 4.2.2 Category 1: Required tests representative for the periodical production control

The following tests shall be performed for periodical production control:

a) bulk density (see 6.1);

b) chemical composition (see 6.2);

c) microstructure (see 6.3);

d) strength (see 6.4).



### 4.2.3 Category 2: Required tests representative for the general material specification

The manufacturer shall define the general material specification. In addition to all tests in 4.2.2, the following tests shall be performed for the qualification of the material specification:

a) Young's modulus (see 6.5);

b) fracture toughness (see 6.6);

c) hardness (see 6.7);

d) wear (see 6.8);

e) cyclic fatigue (see 6.9).

## 4.3 Material properties

To fulfil the requirements of this document, the material shall meet the limits for properties as given in Table 1.