

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा
सर्जरी के लिए प्रत्यारोपण - सिरेमिक सामग्री
भाग 1: उच्च शुद्धता एल्यूमिना पर आधारित सिरेमिक सामग्री

(IS/ISO 6474-1 : 2010 का पहला पुनरीक्षण)

Draft Indian Standard
Implants for Surgery — Ceramic Materials
Part 1: Ceramic Materials Based on High Purity Alumina

(First Revision of IS/ISO 6474-1 : 2010)

ICS 11.040.10

Orthopaedic Instruments, Implants and
Accessories Sectional Committee, MHD 02

Last date for comments: **12 July 2024**

NATIONAL FOREWORD

(Adoption clause will be added later)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian

Standards also exist. The corresponding Indian Standards, which are to be substituted in their places, are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 14704, Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for flexural strength of monolithic ceramics at room temperature	IS 17933 : 2022/ ISO 14704 : 2016 Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for flexural strength of monolithic ceramics at room temperature	Identical
ISO 14705, Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for hardness of monolithic ceramics at room temperature	IS 17991 : 2022/ ISO 14705 : 2016 Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for hardness of monolithic ceramics at room temperature	Identical
ISO 17561, Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for elastic moduli of monolithic ceramics at room temperature by sonic resonance	IS 17981 : 2022/ ISO 17561 : 2016 Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for elastic moduli of monolithic ceramics at room temperature by sonic resonance	Identical
ISO 18754, Fine ceramics (advanced ceramics, advanced technical ceramics) — Determination of density and apparent porosity	IS 17935 : 2022/ ISO 18754 : 2020 Fine ceramics (advanced ceramics, advanced technical ceramics) — Determination of density and apparent porosity	Identical
ISO 20501, Fine ceramics (advanced ceramics, advanced technical ceramics) — Weibull statistics for strength data	IS 17934 : 2022/ ISO 20501 : 2019 Fine ceramics (advanced ceramics, advanced technical ceramics) — Weibull statistics for strength data	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

<i>International Standard/ Other Publication</i>	<i>Title</i>
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 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 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 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

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (Second Revision)'.

Note: The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 6474-1 or kindly contact:

Head (MHD)
Bureau of Indian Standards
Manak Bhawan
9 Bahadur Shah Zafar Marg
New Delhi 110002
Email: hmhd@bis.gov.in; mhd@bis.gov.in

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.