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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 22750.1-2024

Replacing GB/T 22750-2008

**Implants for surgery - Ceramic materials - Part 1: Ceramic
materials based on high purity alumina**

外科植入物 陶瓷材料 第1部分：高纯氧化铝陶瓷材料

(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting is required.

This document is Part 1 of GB/T 22750 "Ceramic materials for surgical implants". GB/T 22750 has been published as follows part.

--Part 1: High purity alumina ceramic materials;

-- Part 2: Zirconia toughened high purity alumina matrix composites.

This document replaces GB/T 22750-2008 "High-purity alumina ceramic materials for surgical implants" and is consistent with GB/T 22750-2008.

In addition to structural adjustments and editorial changes, the main technical changes are as follows.

-- Added "Category 1.Tests required for periodic inspection" (see 4.2.2);

-- Added "Category 2.Tests required by general material specifications" (see 4.2.3);

-- Changed the material properties. Table 1 added the requirements for Young's modulus, fracture toughness, hardness, and cyclic fatigue. The volume density, Chemical composition, microstructure, material strength. and related indicators of wear performance (see 4.3, GB/T 22750-2008 Chapter 4);

--Added sample preparation (see Chapter 5);

--The microstructure test method has been changed, and the requirements for the number

of specimens have been increased (see 6.3, 5.3 of GB/T 22750-2008);

--Changed the strength performance test method, and added the four-point bending strength test and Weibull modulus test (see 6.4, GB/T 22750-5.4 in 2008);

--Added Young's modulus test method (see 6.5);

--Added fracture toughness test methods, including SEVNB, SEPB and SCF test methods (see 6.6);

-- Added hardness test method and adopted Vickers hardness test method (see 6.7);

--Added cyclic fatigue test method (see 6.9).

This document is modified to adopt ISO 6474-1:2019 "Ceramic materials for surgical implants - Part 1: High-purity alumina ceramic materials".

The technical differences between this document and ISO 6474-1:2019 and their reasons are as follows.

--ISO 14704 was replaced by the normative reference GB/T 6569 to adapt to my country's technical conditions and increase operability (see 4.3, 6.4.3);

--ISO 14705 was replaced by the normative reference GB/T 16534 to adapt to my country's technical conditions and increase operability (see 4.3, 6.7);

-- The normative reference GB/T 21114 replaced ISO 12677 to adapt to my country's technical conditions and increase operability (see 4.3, 6.2);

--ISO 15732 was replaced by the normative reference GB/T 23806 to adapt to my country's technical conditions and increase operability (see 4.3, 6.6.3);

-- The normative reference GB/T 25995 replaced ISO 18754 to adapt to my country's technical conditions and increase operability (see 4.3, 6.1);

--ISO 20501 was replaced by the normative reference GB/T 40005 to adapt to my country's technical conditions and increase operability (see 4.3, 6.4.4);

--Replaced ASTM C1499 with the normative reference GB/T 42667 to adapt to my country's technical conditions and increase operability (See 4.3, 6.4.2);

--ISO 22214 was replaced by the normative reference GB/T 43296 to adapt to my country's technical conditions and increase operability (see 4.3, 6.9);

--Replaced ASTM C1259 with the normative reference JC/T 2172 to adapt to my country's technical conditions and increase operability (See 4.3, 6.5);

--ISO 16248 was replaced with the normative reference YY/T 1427 to adapt to my country's technical conditions and increase operability (See 6.9);

--Added reference to GB/T 37248 and further clarified the test method (see 4.3 and 6.2);

--The load for hardness test has been changed and the load requirements have been further clarified (see 6.7, 6.7 of ISO 6474-1:2019).

The following editorial changes have been made to this document.

--Replaced ISO 10993-1 with the informative reference GB/T 16886.1 (see Chapter 1, ISO 6474-1:2019 Chapter 1);

--Added the description of periodic inspection and cited GB/T 2829 for informational purposes (see the note to 4.2.2);

--YY/T 0651.1 replaced ISO 14242-1 (see 4.3, 6.8, 4.3 and 6.8 of ISO 6474-1:2019);

--Added explanation on the method for measuring linear intercept of alumina grains (see Note 2 of 6.3).

Introduction

The durability of artificial joints is closely related to the tribological properties of the prosthesis. Bioceramic materials have excellent tribological properties and good Good biocompatibility is often used as friction pairs in artificial joints.

GB/T 22750 "Ceramic Materials for Surgical Implants" is intended to consist of two parts.

-- Part 1: High-purity alumina ceramic materials. The purpose is to standardize biostable ceramic bone substitute materials based on high-purity alumina.

The properties of materials and corresponding test methods.

-- Part 2: Zirconia toughened high purity alumina matrix composites. The purpose is to standardize the biocompatible and biostable the properties of ceramic bone substitute materials (zirconia toughened high-purity alumina-based composite materials) and corresponding test methods were determined.

There is no known surgical implant material that has been proven to be completely non-toxic to the human body.

The material has been shown in long-term clinical use to have an acceptable level of expected biological response if used appropriately.

Ceramic materials for surgical implants Part 1: High purity alumina ceramic materials

1 Scope

This document specifies the properties of high purity alumina ceramic materials and describes the corresponding test methods.

This document applies to bone spacers, bone replacement materials and orthopedic joint prosthetic components.

This document does not include the content of biocompatibility evaluation (see GB/T 16886.1).

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

GB/T 6569 Test method for flexural strength of fine ceramics (GB/T 6569-2006, ISO 14704:2000, MOD) GB/T 16534 Test method for room temperature hardness of fine ceramics (GB/T 16534-2009, ISO 14705:2008, MOD) GB/T 21114 Refractory materials - X-ray fluorescence spectrochemical analysis - Cast glass disc method (GB/T 21114-2019, ISO 12677:2011, MOD) GB/T 23806 Test method for fracture toughness of fine ceramics - Single edge precracked beam (SEPB) method (GB/T 23806-2009, ISO 15732:2003, MOD) GB/T 25995 Test method for density and apparent porosity of fine ceramics (GB/T 25995-2010, ISO 18754:2003, MOD) GB/T 37248 High-purity alumina-Determination of trace metal elements-Inductively coupled plasma optical emission spectrometry GB/T 40005 Weibull statistical analysis method for strength data of fine ceramics (GB/T 40005-2021, ISO 20501:2019, MOD) GB/T 42667 Fine ceramics - Test method for equibiaxial bending strength at room temperature - Double ring method (GB/T 42667-2023, ISO 17167.

2018, MOD)

GB/T 43296 Test method for room temperature bending fatigue properties of fine ceramics (GB/T 43296-2023, ISO 22214:2006, MOD) JC/T 2172 Test method for elastic modulus, shear modulus and Poisson's ratio of fine ceramics - Pulse excitation method YY/T 1427 Test solutions and conditions for static and dynamic corrosion testing of surgical implants, implantable materials and medical devices ISO 13383-1 Fine ceramics (advanced ceramics, high-tech ceramics) Microstructure characterization Part 1: Grain size and size distribution Determination of cloth [Fine ceramics (advanced ceramics, advanced technical ceramics)-Microstructural characteriza-tion-Part 1: Determination of grain size and size distribution] ISO 17561 Fine ceramics (advanced ceramics, high-tech ceramics) Determination of elastic modulus of bulk ceramics at room temperature by acoustic resonance method Test method [Fine ceramics (advanced ceramics, advanced technical ceramics)-Test method for elastic moduli of monolithic ceramics at room temperature by sonic resonance] ISO 18756 Fine ceramics (advanced ceramics, high-tech ceramics) - Surface crack bending (SCF) method for the determination of the fracture toughness of bulk ceramics at room temperature Fracture toughness [Fine ceramics (advanced ceramics, advanced technical ceramics)-Determination of fracture toughness of monolithic ceramics