

Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) (ISO 13356:2015)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

| | |
|---|--|
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EUROPEAN STANDARD

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Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) (ISO 13356:2015)

Implants chirurgicaux - Produits céramiques à base de zircone tétragonal stabilisée à l'yttrium (Y-TZP) (ISO 13356:2015)

Chirurgische Implantate - Keramische Werkstoffe aus yttriumstabilisiertem tetragonalem Zirkonium (Y-TZP) (ISO 13356:2015)

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 13356:2015) has been prepared by Technical Committee ISO/TC 106 “Dentistry” in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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Endorsement notice

The text of ISO 13356:2015 has been approved by CEN as EN ISO 13356:2015 without any modification.

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Foreword

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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 13356:2008), which has been technically revised.

Introduction

No known surgical implant material has ever been found to cause absolutely no adverse reactions in the human body. However, long-term clinical experience regarding the use of the material referred to in this International Standard has shown that an acceptable level of biological response can be expected if the material will be used in appropriate applications.

Implants for surgery — Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)

1 Scope

This International Standard specifies the requirements and corresponding test methods for a biocompatible and biostable ceramic bone-substitute material based on yttria-stabilized tetragonal zirconia (yttria tetragonal zirconia polycrystal, Y-TZP) for use as a material for surgical implants.

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 3310-1, *Test sieves — Technical requirements and testing — Part 1: Test sieves of metal wire cloth*

ISO 3611, *Geometrical product specifications (GPS) — Dimensional measuring equipment: Micrometers for external measurements — Design and metrological characteristics*

ISO 7500-1, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Verification and calibration of the force-measuring system*

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 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 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*

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

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*

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 E112, *Standard Test Method for Determining Average Grain Size*

3 Physical and chemical properties

The physical and chemical properties, when tested as specified in [Clause 4](#), shall comply with the values specified in [Table 1](#).

3.1 Test category

3.1.1 General

The required tests are divided into two categories.

3.1.2 Category 1

The following test shall be performed for periodical production control:

- a) bulk density;
- b) chemical composition;
- c) microstructure;
- d) strength (including Weibull modulus);
- e) accelerated aging (monoclinic fraction).

3.1.3 Category 2

The manufacturer shall define the general materials specification. In addition to all tests in [3.1.2](#), the following tests shall be performed to demonstrate compliance with the material specification:

- a) hardness;
- b) Young's modulus;
- c) fatigue strength;
- d) accelerated aging (strength);
- e) quantity of monoclinic phase;
- f) radioactivity.