Irish Standard
I.S. EN ISO 13356:2015

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

I.S. EN ISO 13356:2015

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN ISO 13356:2015 is the adopted Irish version of the European Document EN ISO 13356:2015, Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) (ISO 13356:2015)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13356

September 2015

ICS 11.040.40

Supersedes EN ISO 13356:2013

English Version

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)

This European Standard was approved by CEN on 22 August 2015.

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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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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I.S. EN ISO 13356:2015

INTERNATIONAL STANDARD

ISO 13356

Third edition
2015-09-15

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

Implants chirurgicaux — Produits céramiques à base de zircone tétragonal stabilisée à l'yttrium (Y-TZP)

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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).

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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 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*