



SLOVENSKI STANDARD SIST EN ISO 13356:2015

01-december-2015

Nadomešča:
SIST EN ISO 13356:2013

Vsadki (implantati) za kirurgijo - Keramični materiali na osnovi tetragonalnega cirkonija, stabiliziranega z itrijem (Y-TZP) (ISO 13356:2015)

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

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

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

Ta slovenski standard je istoveten z: EN ISO 13356:2015

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
-----------	---	---

SIST EN ISO 13356:2015 en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 13356:2015](#)

<https://standards.iteh.ai/catalog/standards/sist/8d0aa6ec-95fa-4d87-a618-dd2ab03759ad/sist-en-iso-13356-2015>

EUROPEAN STANDARD

EN ISO 13356

NORME EUROPÉENNE

EUROPÄISCHE NORM

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 zirconie tétragonale 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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Contents	Page
European foreword.....	3

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 13356:2015](https://standards.iteh.ai/catalog/standards/sist/8d0aa6ec-95fa-4d87-a618-dd2ab03759ad/sist-en-iso-13356-2015)
<https://standards.iteh.ai/catalog/standards/sist/8d0aa6ec-95fa-4d87-a618-dd2ab03759ad/sist-en-iso-13356-2015>

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.

This document supersedes EN ISO 13356:2013.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

STANDARD PREVIEW

(standards.iteh.ai)

Endorsement notice

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

SIST EN ISO 13356:2015
<https://standards.iteh.ai/catalog/standards/sist/8d0aa0cc-951a-4d87-a018-dd2ab03759ad/sist-en-iso-13356-2015>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 13356:2015](#)

<https://standards.iteh.ai/catalog/standards/sist/8d0aa6ec-95fa-4d87-a618-dd2ab03759ad/sist-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
tétraogonale stabilisée à l'yttrium (Y-TZP)*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 13356:2015](https://standards.iteh.ai/catalog/standards/sist/8d0aa6ec-95fa-4d87-a618-dd2ab03759ad/sist-en-iso-13356-2015)

[https://standards.iteh.ai/catalog/standards/sist/8d0aa6ec-95fa-4d87-a618-
dd2ab03759ad/sist-en-iso-13356-2015](https://standards.iteh.ai/catalog/standards/sist/8d0aa6ec-95fa-4d87-a618-dd2ab03759ad/sist-en-iso-13356-2015)



Reference number
ISO 13356:2015(E)

© ISO 2015

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 13356:2015

<https://standards.iteh.ai/catalog/standards/sist/8d0aa6ec-95fa-4d87-a618-dd2ab03759ad/sist-en-iso-13356-2015>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Physical and chemical properties	2
3.1 Test category.....	2
3.1.1 General.....	2
3.1.2 Category 1.....	2
3.1.3 Category 2.....	2
4 Test methods	4
4.1 General.....	4
4.2 Bulk density.....	4
4.3 Chemical composition.....	4
4.4 Microstructure.....	4
4.4.1 Principle.....	4
4.4.2 Test report.....	5
4.4.3 Amount of monoclinic phase.....	5
4.5 Biaxial flexural strength.....	6
4.5.1 Principle.....	6
4.5.2 Apparatus.....	6
4.5.3 Preparation of test specimens.....	6
4.5.4 Procedure.....	7
4.5.5 Calculation of results.....	8
4.5.6 Test report.....	8
4.6 Four-point bending strength.....	8
4.7 Weibull modulus.....	9
4.8 Young's modulus.....	9
4.9 Hardness.....	9
4.10 Cyclic fatigue.....	9
4.10.1 Principle.....	9
4.10.2 Apparatus.....	9
4.10.3 Sample size and preparation of test specimens.....	9
4.10.4 Procedure and sample requirement.....	9
4.10.5 Test Report.....	10
4.11 Radioactivity.....	10
4.11.1 Principle.....	10
4.11.2 Apparatus.....	10
4.11.3 Sample preparation.....	11
4.11.4 Isotope identification - Energy calibration.....	11
4.11.5 Quantitative analysis.....	11
4.11.6 Expression of results.....	12
4.11.7 Test report.....	12
4.12 Accelerated aging test.....	12
4.12.1 General.....	12
4.12.2 Procedure.....	12
4.12.3 Evaluation of accelerated aging outcome.....	12
Bibliography	13

ISO 13356:2015(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 13356:2015](https://standards.iteh.ai/catalog/standards/sist/8d0aa6ec-95fa-4d87-a618-dd2ab03759ad/sist-en-iso-13356-2015)

<https://standards.iteh.ai/catalog/standards/sist/8d0aa6ec-95fa-4d87-a618-dd2ab03759ad/sist-en-iso-13356-2015>