SLOVENSKI STANDARD
SIST EN ISO 13356:2013

01-september-2013

Vsadki (implantati) za kirurgijo - Keramični materiali na osnovi tetragonalnega cirkonija, stabiliziranega z itrijem (Y-TZP) (ISO 13356:2008)

Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) (ISO 13356:2008)

Chirurgische Implantate - Keramische Werkstoffe aus yttriumstabilisiertem tetragonalem Zirkondioxid (Y-TZP) (ISO 13356:2008)

Implants chirurgicaux - Produits céramiques à base de zircone tétragonal stabilisé à l'oxyde d'yttrium (Y-TZP) (ISO 13356:2008)

Ta slovenski standard je istoveten z: **EN ISO 13356:2013**

ICS:

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

SIST EN ISO 13356:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13356

April 2013

ICS 11.040.40

English Version

Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) (ISO 13356:2008)

Implants chirurgicaux - Produits céramiques à base de zircone tétragonal stabilisé à l'oxyde d'yttrium (Y-TZP) (ISO 13356:2008)

Chirurgische Implantate - Keramische Werkstoffe aus yttriumstabilisiertem tetragonalem Zirkondioxid (Y-TZP) (ISO 13356:2008)

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COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

The text of ISO 13356:2008 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 13356:2013 by 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of an identical text or by endorsement, at the latest by October 2013, and conflicting national standards shall be withdrawn at the latest by October 2013.

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Endorsement notice

The text of ISO 13356:2008 has been approved by CEN as EN ISO 13356:2013 without any modification.

INTERNATIONAL STANDARD

ISO 13356

Second edition
2008-06-01

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

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

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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.

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 13356 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This second edition cancels and replaces the first edition (ISO 13356:1997) which has been technically revised.

Introduction

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