SLOVENSKI STANDARD
oSIST prEN ISO 13356:2026

01-oktober-2026

Vsadki (implantati) za kirurgijo - Aluminijev keramični material: Cirkonij - Tetragonalni cirkonij, stabiliziran z itrijem (Y-TZP) (ISO/DIS 13356:2026)

Implants for surgery - Alumina ceramic material: Zirconia - Yttria-stabilized tetragonal zirconia (Y-TZP) (ISO/DIS 13356:2026)

Chirurgische Implantate - Keramische Werkstoffe: Zirconia - Yttrium-stabilisiertes tetragonales Zirkoniumoxid (Y□TZP) (ISO/DIS 13356:2026)

Implants chirurgicaux - Produits céramiques à base de zircone tétragonal stabilisée à l'yttrium (Y-TZP) (ISO/DIS 13356:2026)

Ta slovenski standard je istoveten z: **prEN ISO 13356**

ICS:

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

oSIST prEN ISO 13356:2026 **en,fr,de**

DRAFT International Standard

ISO/DIS 13356

Implants for surgery — Alumina ceramic material: Zirconia — Yttria-stabilized tetragonal zirconia (Y-TZP)

ICS: 11.040.40

ISO/TC **150**/SC **1**

Secretariat: **DIN**

Voting begins on:
2026-08-26

Voting terminates on:
2026-11-18

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 13356:2026(en)

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Published in Switzerland

Contents

Page

Foreword

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

This forth edition cancels and replaces the third edition (ISO 13356:2015), which has been technically revised.

— title changed to *Implants for surgery —Alumina ceramic material:Zirconia — Yttria-stabilized tetragonal zirconia (Y-TZP)*;

— normative references were updated;

— requirements and normative references in Table 1 were revised;

— the numbers of test specimens for each test item were reviewed;

— the equation for calculating the amount of monoclinic phase was corrected ;

— Testing for radioacitity was moved to an informative annex.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

While no known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body, long-term clinical experience with the material referred to in this document has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications. However, this standard covers the raw material and not finished medical devices, where the design and fabrication of the device can impact biological response.