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Implants for surgery - Metallic materials - Part 2:
Unalloyed titanium (ISO 5832-2:2025)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>See Eesti standard EVS-EN ISO 5832-2:2025 sisaldab Euroopa standardi EN ISO 5832-2:2025 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 17.09.2025.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN ISO 5832-2:2025 consists of the English text of the European standard EN ISO 5832-2:2025.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 17.09.2025.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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ICS 11.040.40

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EUROPEAN STANDARD

EN ISO 5832-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2025

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Supersedes EN ISO 5832-2:2018

English Version

Implants for surgery - Metallic materials - Part 2: Unalloyed titanium (ISO 5832-2:2025)

Implants chirurgicaux - Matériaux métalliques - Partie
2: Titane non allié (ISO 5832-2:2025)

Chirurgische Implantate - Metallische Werkstoffe - Teil
2: Unlegiertes Titan (ISO 5832-2:2025)

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 5832-2:2025) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery " 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of an identical text or by endorsement, at the latest by March 2026, and conflicting national standards shall be withdrawn at the latest by March 2026.

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

This document supersedes EN ISO 5832-2:2018.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 5832-2:2025 has been approved by CEN as EN ISO 5832-2:2025 without any modification.

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Chemical composition	1
5 Microstructure	2
6 Mechanical properties	2
6.1 Tensile properties.....	2
6.2 Bending properties.....	2
7 Test methods	3
Bibliography	4

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).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, SC 1, *Materials* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fifth edition cancels and replaces the fourth edition (ISO 5832-2:2018), which has been technically revised.

The main changes are as follows:

- the introduction has been updated;
- the requirement for cobalt in [Table 1](#) has been added;
- the wording for mechanical properties in [Table 2](#) has been updated;
- this document has been harmonized with the other parts of the ISO 5832 series.

A list of all parts in the ISO 5832 series can be found on the ISO website.

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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 document covers the raw material and not finished medical devices, where the design and fabrication of the device can impact biological response.

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Implants for surgery — Metallic materials —

Part 2: Unalloyed titanium

1 Scope

This document specifies the characteristics of, and corresponding test methods for, unalloyed titanium for use in the manufacture of surgical implants.

Six grades of titanium based on tensile strength are listed in [Table 2](#).

NOTE The mechanical properties of a sample obtained from a finished product made of this metal do not necessarily conform with those specified in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 643, *Steels — Micrographic determination of the apparent grain size*

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 7438, *Metallic materials — Bend test*

ASTM E112, *Standard test methods for determining average grain size*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

4 Chemical composition

The heat analysis when determined as specified in [Clause 7](#) shall conform to the requirements as to chemical composition specified in [Table 1](#). Ingot analysis may be used for reporting all chemical requirements except hydrogen, which shall be determined after the last heat treatment and pickling procedure.