

Implants for surgery - Metallic materials - Part 3:
Wrought titanium 6-aluminium 4-vanadium alloy (ISO
5832-3:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 5832-3:2021 sisaldab Euroopa standardi EN ISO 5832-3:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 5832-3:2021 consists of the English text of the European standard EN ISO 5832-3:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.12.2021.	Date of Availability of the European standard is 01.12.2021.
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English Version

**Implants for surgery - Metallic materials - Part 3: Wrought
titanium 6-aluminium 4-vanadium alloy (ISO 5832-
3:2021)**

Implants chirurgicaux - Matériaux métalliques - Partie
3: Alliage corroyé à base de titane, d'aluminium-6 et de
vanadium-4 (ISO 5832-3:2021)

Chirurgische Implantate - Metallische Werkstoffe - Teil
3: Titan 6-Aluminium 4-Vanadium Knetlegierung (ISO
5832-3:2021)

This European Standard was approved by CEN on 30 October 2021.

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

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European foreword

This document (EN ISO 5832-3:2021) 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of an identical text or by endorsement, at the latest by June 2022, and conflicting national standards shall be withdrawn at the latest by June 2022.

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 5832-3:2016.

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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 5832-3:2021 has been approved by CEN as EN ISO 5832-3:2021 without any modification.

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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.

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*, Subcommittee 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 5832-3:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

- normative references have been updated;
- requirements for microstructure have been clarified in [Clause 5](#);
- the pass/fail criteria for tensile testing of material properties have been clarified in [6.1](#);
- [Table 3](#) on test methods has been updated;
- references to ISO 20160 and EN 3114-03 have been removed from [Annex A](#).

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

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

Implants for surgery — Metallic materials —

Part 3:

Wrought titanium 6-aluminium 4-vanadium alloy

1 Scope

This document specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 6-aluminium 4-vanadium alloy (Ti-6Al-4V alloy) for use in the manufacture of surgical implants.

NOTE The mechanical properties of a sample obtained from a finished product made of this alloy might not necessarily comply with the specifications given 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 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 7438, *Metallic materials — Bend test*

ISO 20160, *Implants for surgery — Metallic materials — Classification of microstructures for alpha+beta titanium alloy bars*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 6892-1 and the following apply.

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/>

3.1

original gauge length

L_0

length between gauge length marks on the test piece measured at room temperature before the test

[SOURCE: ISO 6892-1:2019, 3.1.1]

4 Chemical composition

The heat analysis of a representative sample of the alloy when determined in accordance with [Clause 7](#) shall be in accordance with the chemical composition specified in [Table 1](#).

NOTE 1 Ingot analysis can be used for determining all chemical requirements except hydrogen.

The analysis of hydrogen shall be carried out after the final heat treatment and the final surface treatment.