SLOVENSKI STANDARD
oSIST prEN ISO 5832-3:2020

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Vsadki (implantati) za kirurgijo - Kovinski materiali - 3. del: Titanova 6-aluminijeva 4-vanadijeva zlitina (ISO/DIS 5832-3:2020)

Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO/DIS 5832-3:2020)

Chirurgische Implantate - Metallische Werkstoffe - Teil 3: Titan 6-Aluminium 4-Vanadium Knetlegierung (ISO/DIS 5832-3:2020)

Implants chirurgicaux - Matériaux métalliques - Partie 3: Alliage corroyé à base de titane, d'aluminium-6 et de vanadium-4 (ISO/DIS 5832-3:2020)

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ICS:

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Implants for surgery — Metallic materials —

Part 3:
Wrought titanium 6-aluminium 4-vanadium alloy

Implants chirurgicaux — Produits à base de métaux —

Partie 3: Alliage à forger à base de titane, d'aluminium 6 et de vanadium 4

Please see the administrative notes on page ii

Reference number
ISO/FDIS 5832-3:2016(E)

ISO/CEN PARALLEL PROCESSING

This final draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

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Contents

Page

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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials.*

This fourth edition cancels and replaces the third edition (ISO 5832-3:1996), which has been technically revised.

ISO 5832 consists of the following parts, under the general title *Implants for surgery — Metallic materials:*

— *Part 1: Wrought stainless steel*

— *Part 2: Unalloyed titanium*

— *Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

— *Part 4: Cobalt-chromium-molybdenum casting alloy*

— *Part 5: Wrought cobalt-chromium-tungsten-nickel alloy*

— *Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy*

— *Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy*

— *Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy*

— *Part 9: Wrought high nitrogen stainless steel*

— *Part 11: Wrought titanium 6-aluminium 7-niobium alloy*

— *Part 12: Wrought cobalt-chromium-molybdenum alloy*

— *Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy*

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 part of ISO 5832 has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications.

Implants for surgery — Metallic materials —

Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 6-aluminium 4-vanadium alloy (Ti 6-AI4-V 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 may not necessarily comply with the specifications given in this part of ISO 5832.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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:—[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*

EN 3114-003, *Aerospace series — Test method — Microstructure of (α+β) titanium alloy wrought products — Part 003: Microstructure of plate*

3 Terms and definitions

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

3.1
original gauge length
L_o
length between gauge length marks on the test piece measured at room temperature before the test

[SOURCE: ISO 6892-1:—, 3.1.1]

4 Chemical composition

The heat/ingot analysis of a representative sample of the alloy when determined in accordance with Clause 6 shall comply with the chemical composition specified in Table 1.

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

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

Requirements for the major and minor elemental constituents for titanium 6-aluminium 4-vanadium alloy are listed in Table 1.

1) To be published. (Revision of ISO 6892-1:2009)

Table 1 — Chemical composition

Element	Compositional limits % (m/m)
Aluminium	5,5 to 6,75
Vanadium	3,5 to 4,5
Iron	0,3 max.
Oxygen	0,2 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,015 max.[a]
Titanium	Balance

[a] Except for billets, for which the maximum hydrogen content shall be 0,010 % (m/m).

NOTE 2 A grade with more restrictive limits of oxygen and iron is known under the term “extra low interstitials” (ELI). Commercially available ELI material can also be ordered using this part of ISO 5832. For exact compositional limits of the ELI grade refer to ASTM F136 (UNS R54601) (www.astm.org).

5 Microstructure

The microstructure, when examined as indicated in Table 3, shall be alpha + beta globular and shall correspond to photomicrographs A1 to A9 in ISO 20160 for round bars or 3T1 to 3T13 in EN 3114-003 for sheet and plates (annealed condition each).

6 Mechanical properties

6.1 Tensile

The tensile properties of the alloy, when tested in accordance with Clause 7, shall comply with the values specified in Table 2.

Table 2 — Mechanical properties of wrought titanium 6-aluminium 4-vanadium alloy in annealed condition

Form of alloy	Tensile strength R_m min MPa	Proof stress of nonproportional elongation $R_{p0,2}$ min MPa	Percentage elongation after fracture[a] A min	Mandrel diameter for bend test mm
Sheet and strip[c]	860	780	8	$10 \times t$[b]
Bar[c]	860	780	10	not applicable

[a] Original gauge length L_0 equal to $(5{,}65 \times \sqrt{S_0})$ or 50 mm, where S_0 is the original cross-sectional area in square millimetres. The original gauge length chosen for testing shall be reported with the test results.

[b] t is the thickness of the sheet or strip.

[c] Maximum diameter or thickness is equal to 75 mm.

NOTE For information on the Mechanical Properties Harmonization between ISO and ASTM wrought titanium 6-aluminium 4-vanadium Implant Material Standards, see Annex B.

Should any of the test pieces not meet the specified requirements, or should they break outside the gauge limits, two further test pieces representative of the same batch shall be tested in the same manner. The alloy shall be deemed to comply only if both additional test pieces meet the specified requirements.

