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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 corroyé à base de titane, d'aluminium-6 et de vanadium-4

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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).

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 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*.

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 updated;

— clarification of requirements for microstructure in 5;

— clarification of pass/fail criteria for tensile testing of material properties in 6.1;

— Table 3 on test methods has been updated;

— update of normative Annex A by reference to ISO 20160, reference to EN 3114-03 was deleted.

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

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

ISO 7438, *Metallic materials — Bend test*

ISO 20160:2006, *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 terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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 6892-1:2016, 3.1.1]

4 Chemical composition

The heat/ingot 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 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.

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 document. For exact compositional limits of the ELI grade refer to ASTM F136 (UNS R54601).

5 Microstructure

The microstructure, when examined as indicated in Table 3, shall be globular alpha or elongated globular alpha in a transformed beta matrix with no continuous alpha network at prior beta grain boundaries.

The transverse microstructure for round bars in the annealed condition shall correspond to photomicrographs A1 to A9 in ISO 20160:2006.

6 Mechanical properties

6.1 Tensile

The tensile properties of the alloy, when tested in accordance with Clause 7, shall be in accordance 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	Proof strength or yield strength	Percentage elongation to failure fracture[a]	Mandrel diameter for bend test
Abbrevation	*UTS* R_m	*YS* $R_{p0,2}$	A	
Unit	MPa	MPa		mm
Sheet and strip[c]	≥ 860	≥ 780	≥ 8 %	10 × *t*[b]

[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.

Table 2 *(continued)*

Form of alloy	Tensile strength	Proof strength or yield strength	Percentage elongation to failure fracture[a]	Mandrel diameter for bend test
Abbrevation	*UTS*	*YS*	A	
	R_m	$R_{p0,2}$		
Unit	MPa	MPa		mm
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.

If any of the test pieces fail within the gauge limits and do not meet specified requirements, two retest pieces shall be tested in the same manner, for each failed test piece. The alloy shall be deemed to conform only if both additional test pieces meet the specified requirements.

If a test piece fails outside the gauge limits, the test is acceptable if the percentage elongation after fracture meets the requirements. If the percentage elongation after fracture does not meet requirements the test shall be discarded and a retest shall be performed.

If any of the retests fails to meet the appropriate requirements, the product represented shall be deemed not to conform to this document. However, the manufacturer can, if desired, subject the material to heat treatment again and resubmit it for testing in accordance with this document.

6.2 Bending

Titanium alloy sheet and strip, when tested in accordance with Clause 7, shall not show any cracking on the outside surface of the test piece.

7 Test methods

The test methods used in determining conformity to this document shall be those given in Table 3.

Representative test pieces for the determination of mechanical properties shall be prepared in accordance with ISO 6892-1.

Table 3 — Test methods

Parameter	Relevant clause	Test method
Chemical composition	4	Recognized analytical procedures (ISO methods where these exist)
Microstructure Bar	5	ISO 20160:2016
Mechanical properties	6	
Tensile strength		ISO 6892-1
Proof stress or yield strength		ISO 6892-1
Percentage elongation after fracture		ISO 6892-1