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Implants for surgery — Metallic materials —

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

Implants chirurgicaux — Matériaux métalliques —

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*, 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 terminological 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_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 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.

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 mass fraction %
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 of a mass fraction of 0,010 %.

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 equiaxed alpha or elongated primary alpha in a transformed beta matrix with no continuous alpha network at prior beta grain boundaries.

NOTE 1 Portions of the microstructure requirements have been extracted from ASTM F136 and ASTM F1472, copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken PA 19428. Copies of these complete standards can be obtained from ASTM.

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

NOTE 2 For a brief description of ISO 20160, see Annex A.

The microstructure of sheets and plates shall be determined and agreed between the manufacturer and the user.

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

Material shape	Tensile strength R_m MPa	Proof strength or yield strength $R_{p0,2}$ MPa	Percentage elongation to failure fracture[a] A	Mandrel diameter for bend test mm
Sheet and strip[c]	≥860	≥780	≥8 %	10 × t[b]
Bar[c]	≥860	≥780	≥10 %	not applicable

[a] The 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] The 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 Tables B.1 and B.2.

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 it meets the specified requirements. If it does not meet specified 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 of this document	Test method
Chemical composition	Clause 4	Recognized analytical procedures (ISO methods where these exist)
Microstructure Bar	Clause 5	ISO 20160
Mechanical properties	Clause 6	
Tensile strength		ISO 6892-1
Proof stress or yield strength		ISO 6892-1
Percentage elongation after fracture		ISO 6892-1
Bending		ISO 7438 Bend the sheet or strip through an angle of 105° around a mandrel of the diameter specified in Table 2.