BS EN ISO 5832-3:2016



BSI Standards Publication

Implants for surgery — Metallic materials

Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3:2016)

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 5832-3:2016. It supersedes BS EN ISO 5832-3:2012 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/1, Materials for surgical implants.

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European foreword

This document (EN ISO 5832-3:2016) 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of an identical text or by endorsement, at the latest by May 2017, and conflicting national standards shall be withdrawn at the latest by May 2017.

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Endorsement notice

The text of ISO 5832-3:2016 has been approved by CEN as EN ISO 5832-3:2016 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 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*

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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.

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INTERNATIONAL STANDARD ISO 5832-3:2016(E)

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)

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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	Proof stress of nonproportional elongation	Percentage elongation after fracture[a]	Mandrel diameter for bend test
	R_m min MPa	$R_{p0,2}$ min MPa	A min	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.

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However, the manufacturer may re-heat-treat the material and resubmit it for testing in accordance with this part of ISO 5832. In this case, all parts shall be heat-treated in the same fashion.

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 compliance with this part of ISO 5832 shall be those given in Table 3.

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

Table 3 — Test methods

Parameter	Relevant clause	Test method
Chemical composition	4	Recognized analytical procedures (ISO methods where these exist)
Microstructure	5	
Bar		ISO 20160
Sheet and strip		EN 3114–003
Mechanical properties	6	
Tensile strength		ISO 6892-1
Proof stress of nonproportional elongation		ISO 6892-1
Percentage elongation		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.

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Annex A
(normative)

Catalogues of metallographic micrographs of typical alpha+beta titanium microstructures

In this annex, two different standards are referenced showing microstructures of typical alpha+beta titanium alloy Ti 6Al 4V intended for the use of identification and classification of the microstructure of a given material. ISO 20160 is presenting microstructures in the transverse section at ×200 magnification. ISO 20160 applies to round bars up to a nominal diameter of 100 mm. It was replacing ETTC 2 Edition 2.

Microstructures of flat rolled products, like sheet or plates, cannot be rated according to ETTC 2. For this type of product, another microstructural catalogue was made available. ETTC 4 Edition 2 is showing microstructures in the transverse section at ×100 and ×500 magnification. Product sizes of this catalogue were limited to a range of thicknesses above 5 mm and below 30 mm. The same microstructures are shown in EN 3114-003 but with different designations. Table A.1 shows the correlation of the designations of the micrographs between ETTC 4 Edition 2 and EN 3114-003.

ETTC4 Edition 2 is showing acceptable microstructures in the range of P1 to P36 for Standard Aerospace Quality (STQ). For medical application, the range of acceptable microstructures is intentionally limited to P1 (3T1) to P13 (3T13) at ×100 magnification showing globular structures.

ETTC 4 Edition 2 is considering only plates, i.e. products over or equal 5 mm in thickness. It is recommended here to use the microstructural pictures also for sizes equal to or below 5 mm.

Table A.1 — Correlation between designations of micrographs ETTC 4 Edition 2 versus EN 3114–003

ETTC 4 Edition 2	EN 3114–003
P1	3T1
P2	3T2
P3	3T3
P4	3T4
P5	3T5
P6	3T6
P7	3T7
P8	3T8
P9	3T9
P10	3T10
P11	3T11
P12	3T12
P13	3T13

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Annex B
(informative)

Mechanical Properties Harmonization between ISO and ASTM wrought titanium 6-aluminium 4-vanadium Implant Material Standards

It is recognized that material suppliers might intend to sell their products around the world. Therefore, this annex is intended to provide mechanical property information for those products which might be required to conform to the relevant wrought titanium 6-aluminium 4-vanadium Implant Material Standards from both ISO and ASTM.

Table B.1 — Mechanical Properties Harmonization for ELI grade (ISO 5832-3 and ASTM F136–13)

ISO + ASTM specification	Material shape	Material size mm	UTS MPa	YS MPa	A %	Z %	Bend test mandrel diameter
ISO 5832-3 + ASTM F136–13	Bar	$d < 4{,}75$	≥860	≥795	≥10	—	—
		$4{,}75 \leq d < 44{,}45$	≥860	≥795	≥10	≥25	—
		$44{,}45 \leq d < 63{,}50$	≥860	≥780	≥10	≥20	—
		$63{,}50 \leq d \leq 75$[a]	≥860	≥780	≥10	≥15	—
	Sheet and strip	$t < 4{,}75$	≥860	≥795	≥10	—	$10 \times t$
		$4{,}75 \leq t < 4{,}76$	≥860	≥795	≥10	≥25	$10 \times t$
		$4{,}76 \leq t < 44{,}45$	≥860	≥795	≥10	≥25	—
		$44{,}45 \leq t < 63{,}50$	≥860	≥780	≥8	≥20	—
		$63{,}50 \leq t < 75$[a]	≥860	≥780	≥8	≥15	—

[a] Material diameter or thickness limit defined in this part of ISO 5832.

NOTE Portions of this table have been extracted from ASTM F136–13, copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken PA 19428. A copy of the complete standard can be obtained from ASTM (www.astm.org).

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Table B.2 — Mechanical Properties Harmonization for non-ELI grade (ISO 5832-3 and ASTM F1472–14)

ISO + ASTM specification	Material shape	Material size mm	UTS MPa	YS MPa	A %	Z %	Bend test mandrel diameter
ISO 5832-3 + ASTM F1472–14	Bar	$d < 50$	≥930	≥860	≥10	≥25	—
		$50 \leq d \leq 75$[a]	≥895	≥825	≥10	≥25	—
	Sheet and Strip	$t < 0{,}2$	≥924	≥869	—	—	$10 \times t$
		$0{,}2 \leq t < 0{,}6$	≥924	≥869	≥6	—	$10 \times t$
		$0{,}6 \leq t < 1{,}6$	≥924	≥869	≥8	—	$10 \times t$
		$1{,}6 \leq t < 4{,}76$	≥924	≥869	≥10	—	$10 \times t$
		$4{,}76 \leq t < 75$[a]	≥895	≥825	≥10	≥20	—

[a] Material diameter or thickness limit defined in this part of ISO 5832.

NOTE Portions of this table have been extracted from ASTM F1472–14, copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken PA 19428. A copy of the complete standard can be obtained from ASTM (www.astm.org).

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[1] ASTM F136-13, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*

[2] ASTM F1472-14, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications (UNS R56400)*

[3] Publication ETTC 2 Edition 2, Microstructural standards for alpha+beta titanium alloy bars, prepared by the Technical Committee of European Titanium producers, 1995. (out of print)

[4] Publication ETTC 4, Edition 2, Microstructural standards for alpha+beta titanium alloy bars, prepared by the Technical Committee of European Titanium producers, 1991. (out of print)

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