TC150

INTERNATIONAL STANDARD

ISO 5832-10

Second edition
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Implants for surgery — Metallic materials —

Part 10:
Wrought titanium 5-aluminium 2,5-iron alloy

Implants chirurgicaux — Produits à base de métaux —

Partie 10: Alliage à forger à base de titane, d'aluminium 5 et de fer 2,5

Reference number
ISO 5832-10:1996(E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 5832-10 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This second edition cancels and replaces the first edition (ISO 5832-10: 1993), 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*

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— *Part 9: Wrought high nitrogen stainless steel*

— *Part 10: Wrought titanium 5-aluminium 2,5-iron alloy*

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

— *Part 12: Wrought cobalt-chromium-molybdenum 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 10:
Wrought titanium 5-aluminium 2,5-iron alloy

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 5-aluminium 2,5-iron alloy (Ti 5-Al 2,5-Fe) for use in the manufacture of surgical implants.

NOTE 1 The mechanical properties of a sample obtained from a finished product made of this alloy may therefore not necessarily comply with the specifications given in this part of ISO 5832.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5832. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5832 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6892:1984, *Metallic materials — Tensile testing.*

ISO 7438:1985, *Metallic materials — Bend test.*

ETTC[1] Publication 2, 1979, *Microstructural standards for* $\alpha + \beta$ *titanium alloy bars*[2].

3 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 2 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 5-aluminium 2,5-iron alloy are listed in table 1.

Table 1 — Chemical composition

Element	Compositional limits, % (*m/m*)
Aluminium	4,5 to 5,5
Iron	2,0 to 3,0
Oxygen	0,20 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,015 max.[1]
Titanium	Balance

1) Except for billets, for which the maximum hydrogen content shall be 0,010 % (*m/m*).

1) European Titanium Producers' Technical Committee (ETTC).

2) Available commercially from: Deutsche Titan GmbH, Essen, Germany and IMI-Titanium Ltd., Birmingham, UK. This information is given for the convenience of users of this part of ISO 5832, and does not constitute an endorsement by ISO of these products.

4 Microstructure

The microstructure, when examined as indicated in table 3, shall be alpha + beta globular, and shall correspond to photomicrographs A1 to A9 in ETTC Publication 2 for annealed material.

5 Mechanical properties

5.1 Tensile

The tensile properties of the alloy, when tested in accordance with clause 6, shall comply with the values specified in table 2.

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.

NOTE 3 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 should be heat-treated in the same fashion.

5.2 Bending

Titanium alloy sheet and strip, when tested in accordance with clause 6, shall not show any cracking on the outside surface of the test piece.

6 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.

Table 2 — Mechanical properties of wrought titanium 5-aluminium 2,5-iron alloy in the 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[1] A min.	Mandrel diameter for bend test
Sheet and strip	900	800	8	10 t[2]
Bar[3]	900	800	10	not applicable

1) Gauge length $= 5{,}65\sqrt{S_o}$ or 50 mm, where S_o is the original cross-sectional area, in square millimetres.

2) t = thickness of the sheet or strip.

3) Maximum diameter or thickness = 75 mm.

Table 3 — Test methods

Parameter	Relevant clause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Microstructure	4	ETTC 2
Mechanical properties	5	
Tensile strength		ISO 6892
Proof stress of nonproportional elongation		ISO 6892
Percentage elongation		ISO 6892
Bending		ISO 7438 Bend the sheet or strip through an angle of 105° around a mandrel of the diameter specified in table 2.

ICS 11.040.40

Descriptors: medical equipment, surgical implants, metallurgical products, wrought products, titanium alloys, aluminium containing alloys, iron containing alloys, specifications, materials specifications, chemical composition, mechanical properties, tests.

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