TC 150

INTERNATIONAL STANDARD

ISO 5832-10

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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 5832-10:1993(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*, Sub-Committee SC 1, *Materials*.

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*

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— *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 be completely free of adverse reactions in the human body. However, long-term clinical experience of use of the material referred to in this part of ISO 5832 has shown that the risk of reaction is low and the advantages of its use outweigh any such risk factor. Therefore, the possibility of such risk should be considered acceptable.

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, 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 depend on the thermo-mechanical treatment undergone, and may therefore not necessarily comply with those specified 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.*

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

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

2) Available from:

Cézus, Usine d'Ugine, Ugine, France;
Deutsche Titan GmbH, Essen, Germany;
IMI - Titanium Ltd., Birmingham, United Kingdom.

3 Chemical composition

The heat analysis when determined as specified in clause 6 shall conform to the requirements as to chemical composition specified in table 1. Ingot analysis may be used for reporting all chemical requirements except hydrogen, which shall be determined after the last heat treatment and pickling procedure.

Table 1 — Chemical composition

Element	Compositional limits, % (*m/m*)
Aluminium	4,5 to 5,5
Iron	2 to 3
Oxygen	0,2 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,013 max.[1]
Titanium	Balance

1) Except for billets, for which the maximum hydrogen content shall be 0,01 % (*m/m*).

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 Publication

ETTC 2 for annealed material. The alloy shall be free of visible inclusions at magnification × 200.

5 Mechanical properties

5.1 Tensile properties

The tensile properties of the alloy, determined as specified in clause 6, shall be in accordance with the requirements of 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.

If any of the retests fails to meet the appropriate requirements, the product represented shall be deemed not to comply with this part of ISO 5832.

However, the manufacturer may, if he so desires, reheat-treat the material and resubmit it for testing in accordance with the requirements of this part of ISO 5832.

5.2 Bending properties

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

6 Test methods

The test methods to be used in determining compliance with the requirements of 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

Form of alloy	Condition	Tensile strength min. MPa	Proof stress of non-proportional elongation min. MPa	Percentage elongation min. %	Reduction of area min. %	Mandrel diameter for bend test[1]
Sheet and strip	annealed	900	800	8	not applicable	10 t
Bar[2]	annealed	900	800	10	25	not applicable

1) t = thickness of the sheet or strip

2) Maximum diameter or thickness = 75 mm

Table 3 — Test methods

Requirement	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 non-proportional elongation		ISO 6892
Percentage elongation		ISO 6892
Reduction of area		ISO 6892
Bending		ISO 7438 Bend the sheet or strip through an angle of 105° around a mandrel of the appropriate diameter specified in table 2.

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

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