INTERNATIONAL STANDARD

ISO 5832-11

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Implants for surgery — Metallic materials —

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

Implants chirurgicaux — Produits à base de métaux —

Partie 11: Alliage à forger à base de titane, d'aluminium 6 et de niobium 7

INTERNATIONAL ISO

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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.

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 5832-11 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee 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*

— *Part 13: Wrought austenitic-ferritic stainless steel*

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 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 11:
Wrought titanium 6-aluminium 7-niobium 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 7-niobium alloy (titanium 6-Al 7-Nb) 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 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.*

Publication ETTC 2,[1] *Microstructural standards for α + β titanium alloy bars, 1979.*[2]

3 Chemical composition

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

Table 1

Element	Compositional limits % (*m/m*)
Aluminium	5,5 to 6,5
Niobium	6,5 to 7,5
Tantalum	0,50 max.
Iron	0,25 max.
Oxygen	0,20 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,009 max.
Titanium	Balance

1) European Titanium Producers Technical Committee (ETTC).

2) Available from:

Cézus, usine d'Ugine, BP 33, 73400 Ugine, France;
Deutsche Titan GmbH, Essen, Germany;
IMI — Titanium Ltd., Birmingham, United Kingdom.

4 Microstructure

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

5 Mechanical 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 fail 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.

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 of alloy in annealed condition

Form of alloy	Tensile strength min. MPa	Proof stress of non-proportional elongation min. MPa	Percentage elongation min. %	Reduction of area min. %
Bar[1)]	900	800	10	25
1) Maximum diameter or thickness = 100 mm				

Table 3 — Test methods

Requirement	Relevant clause	Test methods
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

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

Price based on 2 pages