INTERNATIONAL STANDARD

ISO 5832-2

Second edition
1993-09-15

Implants for surgery — Metallic materials —

Part 2: Unalloyed titanium

Implants chirurgicaux — Produits à base de métaux —
Partie 2: Titane non allié

INTERNATIONAL ISO

Reference number
ISO 5832-2:1993(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 5832-2 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*

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland
Printed in Switzerland

— *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 2:
Unalloyed titanium

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, unalloyed titanium for use in the manufacture of surgical implants.

Provision is made for five grades of titanium based on tensile strength (see table 2).

NOTE 1 The mechanical properties of a sample obtained from a finished product made of this metal 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.*

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

ASTM E 112:1988, *Methods for determining Average Grain Size.*

3 Chemical composition

The heat analysis when determined as specified in clause 6 shall conform to the requirements as to chemical composition prescribed 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.

4 Microstructure

The microscopic structure of the titanium in the annealed condition shall be uniform. The grain size, determined as specified in clause 6, shall be no coarser than grain size No. 5.

5 Mechanical properties

5.1 Tensile properties

The tensile properties of the titanium, 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 titanium 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, re-heat-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 1 — Chemical composition

Element	Compositional limits, % (*m/m*)			
	Grade 1 max.	Grade 2 max.	Grade 3 max.	Grades 4A and 4B max.
Nitrogen	0,03	0,03	0,05	0,05
Carbon	0,1	0,1	0,1	0,1
Hydrogen	0,012 5 [1)]	0,012 5 [1)]	0,012 5 [1)]	0,012 5 [1)]
Iron	0,15	0,2	0,25	0,3
Oxygen	0,18	0,25	0,35	0,45
Titanium	Balance	Balance	Balance	Balance

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

Table 2 — Mechanical properties

Grade	Condition	Tensile strength[1)] min. MPa	Proof stress of non-proportional elongation[1)] min. MPa	Percentage elongation min. %	Reduction of area (bars and billets only) min. %	Mandrel diameter for bend test for sheet and strip[2)] mm where $t < 2$ mm	 where $2 \text{ mm} \leqslant t \leqslant 5$ mm
1	annealed	240	170	24	30	3 t	4 t
2	annealed	345	230	20	30	4 t	5 t
3	annealed	450	300	18	30	4 t	5 t
4A	annealed	550	440	15	25	5 t	6 t
4B	cold-worked	680	520	10	18	6 t	7 t

1) Tensile, yield and bending requirements of sheet shall apply to material taken both parallel and perpendicular to the direction of rolling.

2) t = thickness of the sheet or strip

Table 3 — Test methods

Requirement	Relevant clause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Grain size	4	ASTM E 112
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 105° around the mandrel of the appropriate diameter specified in table 2.

UDC 616-089.843:615.465:669.295

Descriptors: surgical implants, metallurgical products, titanium, specifications, materials specifications, chemical composition, mechanical properties, tests.

Price based on 3 pages