INTERNATIONAL STANDARD

ISO 5832-2

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Implants for surgery — Metallic materials —

Part 2:
Unalloyed titanium

Implants chirurgicaux — Produits à base de métaux —

Partie 2: Titane non allié

Reference number
ISO 5832-2:1999(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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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*, Subcommittee SC 1, *Materials*.

This third edition cancels and replaces the second edition (ISO 5832-2:1993), 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*

— *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*

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

Printed in Switzerland

Introduction

No known surgical implant material has ever been shown to cause absolutely no adverse reaction 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 — Metalic 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 six grades of titanium based on tensile strength (see Table 2).

NOTE 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 normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 6892:1998, *Metallic materials — Tensile testing at ambient temperature.*

ISO 7438:1995, *Metallic materials — Bend test.*

ASTM E 112:1988, *Standard Test 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 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.

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.

At a magnification of 100×, no inclusions or foreign phases shall be visible.

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, 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 a test piece fails outside the gauge limits, the test is invalid and a retest shall be performed.

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

Table 1 — Chemical composition

Element	Maximum compositional limits percent mass fraction				
	Grade 1 ELI	**Grade 1**	**Grade 2**	**Grade 3**	**Grades 4A and 4B**
Nitrogen	0,012	0,03	0,03	0,05	0,05
Carbon	0,03	0,10	0,10	0,10	0,10
Hydrogen	0,012 5 [a]	0,012 5 [a]	0,012 5 [a]	0,012 5 [a]	0,012 5 [a]
Iron	0,10	0,20	0,30	0,30	0,50
Oxygen	0,10	0,18	0,25	0,35	0,40
Titanium	Balance	Balance	Balance	Balance	Balance

[a] Except for billets, for which the maximum hydrogen content shall be 0,010 0 % (mass fraction) and for flat products for which the maximum hydrogen content shall be 0,015 % (mass fraction).

Table 2 — Mechanical properties

Grade	Condition	Tensile stength [a]	Proof stress of non-proportional elongation	Percentage elongation [b]	Mandrel diameter for bend test for sheet and strip [c]	
		min.	min.	min.	mm	
		MPa	MPa	%	where	where
					$t \leqslant 2$ mm	2 mm < t < 5 mm
1 ELI	Annealed	200	140	30	3 t	4 t
1	Annealed	240	170	24	3 t	4 t
2	Annealed	345	275	20	4 t	5 t
3	Annealed	450	380	18	4 t	5 t
4A	Annealed	550	483	15	5 t	6 t
4B	Cold-worked	680	520	10	6 t	6 t

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

[b] Gauge length = 5,65 $\sqrt{S_0}$ or 50 mm, where S_0 is the original cross-sectional area, in square millimetres.

[c] t = thickness of the sheet or strip.

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 3 — Methods of test

Requirement	Relevant clause	Method of test
Chemical composition	3	Recognized analytical procedures
Grain size	4	ASTM E 112
Mechanical properties	5	
Ultimate tensile strength		ISO 6892
Yield strength		ISO 6892
Elongation		ISO 6892
Reduction of area		ISO 6892
Bend test		ISO 7438 Bend the sheet or strip through an angle of at least 105° around a mandrel of the diameter specified in Table 2

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