INTERNATIONAL STANDARD

ISO 5832-14

First edition
2007-10-15

Implants for surgery — Metallic materials —

Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy

Implants chirurgicaux — Matériaux métalliques —

Partie 14: Alliage corroyé à base de titane, de molybdène-15, de zirconium-5 et d'aluminium-3

Reference number
ISO 5832-14:2007(E)

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Published in Switzerland

Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 5832-14 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*

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

— *Part 12: Wrought cobalt-chromium-molybdenum alloy*

— *Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium 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 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, the wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy for use in the manufacture of surgical implants.

This part of ISO 5832 applies to materials in bar form up to a maximum diameter of 100 mm.

NOTE The mechanical properties of a sample obtained from a finished product made of this alloy can differ from those specified in this part of ISO 5832.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 643, *Steels — Micrographic determination of the apparent grain size*

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

3 Chemical composition

The heat analysis when determined as specified in Clause 6 shall comply with the 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 Percent mass fraction
Molybdenum	14,0 to 16,0
Zirconium	4,5 to 5,5
Aluminium	2,5 to 3,5
Iron	0,30 max.
Oxygen	0,20 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,02 max.
Titanium	Balance

4 Microstructure

The microscopic structure of the alloy in the solution annealed condition shall be uniform and fully recrystallized single-phase beta microstructure. The grain size, determined as specified in Clause 6, shall be no coarser than grain size No. 4. at a magnification of 100 ×, and no alpha case or other foreign phases shall be visible.

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 specified requirements, 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 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, subject the material to heat treatment again and resubmit it for testing in accordance with this part of ISO 5832.

Table 2 — Mechanical properties of bars

Condition	Tensile strength $R_{m,min}$ MPa	Proof stress $R_{p0.2min}$ MPa	Elongation A_{min} %
Solution annealed [a]	900	800	12

[a] Maximum diameter = 100 mm.

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 — Test methods

Parameter	Relevant clause	Test method
Chemical composition	3	Recognized analytical procedures
Grain size	4	ISO 643
Tensile properties	5	ISO 6892

Bibliography

[1] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ICS 11.040.40

Price based on 3 pages