
**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)

© ISO 2007

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.



COPYRIGHT PROTECTED DOCUMENT

© ISO 2007

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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 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	Proof stress	Elongation
	$R_{m,min}$ MPa	$R_{p0,2min}$ MPa	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*

© ISO 2007. All rights reserved.

ICS 11.040.40

Price based on 3 pages