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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

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Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery,* Subcommittee SC 1, *Materials*.

This second edition cancels and replaces the first edition (ISO 5832-14:2007), which has been technically revised.

A list of all parts in the ISO 5832 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 document 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 document 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 document 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 document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Chemical composition

The heat analysis when determined as specified in Clause 7 shall conform to 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 Mass fraction %
Molybdenum	14,0 to 16,0
Zirconium	4,5 to 5,5
Aluminium	2,5 to 3,5
Iron	0,30 maximum
Oxygen	0,20 maximum
Carbon	0,08 maximum
Nitrogen	0,05 maximum
Hydrogen	0,02 maximum
Titanium	Balance

5 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 7, 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.

6 Mechanical properties

The tensile properties of the alloy, determined as specified in Clause 7, shall be in accordance with the requirements of Table 2.

If any of the test pieces fail within the gauge limits and do not meet specified requirements, two retest pieces shall be tested in the same manner, for each failed test piece. The alloy shall be deemed to conform only if both additional test pieces meet the specified requirements.

If a test piece fails outside the gauge limits, the test is acceptable if the percentage elongation after fracture meets the requirements. If the percentage elongation after fracture does not meet requirements the test shall be discarded 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 conform to this document. However, the manufacturer can, if desired, subject the material to heat treatment again and resubmit it for testing in accordance with this document.

Table 2 — Mechanical properties of bars

Condition	Tensile strength R_m MPa minimum	Yield strength or proof strength $R_{p0,2}$ MPa minimum	Percentage elongation after fracture A % minimum
Solution annealed[a]	900	800	12
[a] Maximum diameter = 100 mm.			

7 Test methods

The test methods to be used in determining conformity to the requirements of this document shall be those given in Table 3.

Representative test pieces for the determination of mechanical properties shall be prepared in accordance with ISO 6892-1.

Table 3 — Test methods

Parameter	Relevant clause	Test method
Chemical composition	4	Recognized analytical procedures
Grain size	5	ISO 643
Mechanical properties	6	ISO 6892-1