## INTERNATIONAL STANDARD



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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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## Foreword

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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 <a href="https://www.iso.org/directives">www.iso.org/directives</a>).

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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 <u>www.iso.org/members.html</u>.

## 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 <a href="https://www.iso.org/obp">https://www.iso.org/obp</a>
- IEC Electropedia: available at http://www.electropedia.org/

#### 4 Chemical composition

The heat analysis when determined as specified in <u>Clause 7</u> shall conform to the chemical composition specified in <u>Table 1</u>. Ingot analysis may be used for reporting all chemical requirements except hydrogen, which shall be determined after the last heat treatment and pickling procedure.