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Fifth edition
2021-11

Implants for surgery — Metallic materials —

Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

Implants chirurgicaux — Matériaux métalliques —

Partie 3: Alliage corroyé à base de titane, d'aluminium-6 et de vanadium-4



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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Chemical composition	1
5 Microstructure	2
6 Mechanical properties	2
6.1 Tensile.....	2
6.2 Bending.....	3
7 Test methods	3
Annex A (informative) Catalogues of metallographic micrographs of typical alpha+beta titanium microstructures	5
Annex B (informative) Mechanical properties' harmonization between ISO and ASTM wrought titanium 6-aluminium 4-vanadium implant material standards	6
Bibliography	8

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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).

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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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fifth edition cancels and replaces the fourth edition (ISO 5832-3:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

- normative references have been updated;
- requirements for microstructure have been clarified in [Clause 5](#);
- the pass/fail criteria for tensile testing of material properties have been clarified in [6.1](#);
- [Table 3](#) on test methods has been updated;
- references to ISO 20160 and EN 3114-03 have been removed from [Annex A](#).

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.

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Introduction

While no known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body, long-term clinical experience with 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. However, this document covers the raw material and not finished medical devices, where the design and fabrication of the device can impact biological response.