INTERNATIONAL STANDARD

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Second edition
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Implants for surgery — Metallic materials —

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

Implants chirurgicaux — Produits à base de métaux —

Partie 11: Alliage à forger à base de titane, d'aluminium 6 et de niobium 7

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This second edition cancels and replaces the first edition (ISO 5832-11:1994), which has been technically revised.

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 be completely free of 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 11: Wrought titanium 6-aluminium 7-niobium alloy

1 Scope

This part of ISO 5832 specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 6-aluminium 7-niobium alloy (Ti-6-Al 7-Nb) for use in the manufacture of surgical implants.

NOTE The mechanical properties of a sample obtained from a finished product made of this alloy might not necessarily comply with those specified in this part of ISO 5832.

2 Normative references

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

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 20160:2006, *Implants for surgery — Metallic materials — Classification of microstructures for alpha+beta titanium alloy bars*

3 Chemical composition

The heat analysis shall conform to the requirements as to the chemical composition prescribed in Table 1. Ingot analysis can be used for reporting all chemical requirements except hydrogen, which shall be determined after the heat treatment and pickling procedure.

Table 1

Element	Compositional limits % (m/m)
Aluminium	5,5 to 6,5
Niobium	6,5 to 7,5
Tantalum	0,50 max.
Iron	0,25 max.
Oxygen	0,20 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,009 max.
Titanium	Balance