



**International  
Standard**

**ISO 5832-11**

**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*

**Third edition  
2024-03**

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Published in Switzerland

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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 document 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](http://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](http://www.iso.org/iso/foreword.html).

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

This third edition cancels and replaces the second edition (ISO 5832-11:2014), which has been technically revised.

The main changes are as follows:

- the introduction has been updated;
- [Clause 4](#) on chemical composition has been updated;
- the mechanical testing language has been updated;
- this document has been harmonized with the ISO 5832 series.

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](http://www.iso.org/members.html).

## 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.

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# Implants for surgery — Metallic materials —

## Part 11:

# Wrought titanium 6-aluminium 7-niobium alloy

## 1 Scope

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

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 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 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 6892-1 apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

## 4 Chemical composition

The heat analysis of a representative sample of the alloy when determined in accordance with [Clause 7](#) shall be in accordance with the chemical composition specified 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 — Chemical composition

Element	Mass fraction of compositional limits %
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

## 5 Microstructure

The microstructure shall be uniform. The microstructure, when examined as indicated in [Table 3](#), shall be globular alpha or elongated globular alpha in a transformed beta matrix with no continuous alpha network at prior beta grain boundaries. The transverse microstructure for round bars in the annealed condition shall correspond to the photomicrographs A1 to A9 of ISO 20160:2006.

## 6 Mechanical properties

The tensile properties of the alloy, determined as specified in [Clause 7](#), shall be in accordance with the values specified 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 it meets the specified requirements. If it does not meet specified 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 alloy in annealed condition

Form of alloy	Minimum tensile strength $R_{m,min}$ MPa	Minimum proof strength or yield strength $R_{p0,2,min}$ MPa	Minimum percentage elongation after fracture <sup>a</sup> $A_{min}$ %	Minimum reduction of area $Z_{min}$ %
bar	900	800	10	25

<sup>a</sup> Maximum diameter or thickness is equal to 100 mm.

## 7 Test methods

The test methods to be used to determine conformity with 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.