	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 ISO/PRF 5832-11 https://standards.iteh.ai/catalog/standards/iso/234264e0-1e3e-444f	iteh.ai) riew
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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 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).

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

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

The main changes are as follows:

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- <u>Clause 4</u> 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 <u>www.iso.org/members.html</u>.

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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