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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 4234.11-2025

Replacing GB 23102-2008

**Implants for surgery - Metallic materials - Part 11: Wrought
titanium 6-aluminium 7-niobium alloy**

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1.Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is Part 11 of GB 4234 "Metallic Materials for Surgical Implants". GB 4234 has already published the following parts.

- Part 1.Forged Stainless Steel;
- Part 2.Pure Titanium;
- Part 3.Forged Titanium-6 Aluminum-4 Vanadium Alloy;
- Part 4.Casting Cobalt-Chromium-Molybdenum Alloys;
- Part 7.Malleable and Cold-Workable Cobalt-Chromium-Nickel-Molybdenum-Iron Alloys;
- Part 9.Forged High-Nitrogen Stainless Steel;
- Part 11.Forged Titanium-6 Aluminum-7 Niobium Alloy;
- Part 12.Forged Cobalt-Chromium-Molybdenum Alloys

This document supersedes GB 23102-2008 "Metallic Materials for Surgical Implants - Ti-6Al-7Nb Alloy Processed Materials", and is consistent with GB 23102-

Compared to.2008, aside from structural adjustments and editorial changes, the main

technical changes are as follows.

---The scope of application has been changed (see Chapter 1, Chapter 1 of GB 23102-2008), adding "This document applies to surgical implants..."

Test and evaluation of forged titanium-6 aluminum-7 niobium alloy;

---Added terms and definitions (see Chapter 3);

---The requirements for chemical composition testing samples have been changed (see Chapter 4, Chapter 3 of GB 23102-2008);

---Added description of microstructure morphology (see Chapter 5);

---The judgment principles for mechanical tests have been changed (see Chapter 6, Chapter 5 of GB 23102-2008);

---The microscopic tissue testing method has been changed (see Table 3, Table 3 in GB 23102-2008).

This document is modified to adopt ISO 5832-11:2024 "Metallic materials for surgical implants - Part 11. Forged titanium-6 aluminum-7 niobium alloys".

The technical differences between this document and ISO 5832-11:2024, and the reasons therefor, are as follows.

---ISO 6892-1 has been replaced with the normatively referenced GB/T 228.1 to adapt to my country's technical conditions (see Chapters 3 and 7);

---Appendix A (Normative) has been added, showing typical microstructure classification diagrams of alpha and beta titanium alloy bars (see Appendix A) for easier use.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed and is under the jurisdiction of the National Medical Products Administration.

The release history of this document and the document it replaces is as follows.

---First published in 2008 as GB 23102-2008;

Introduction

Implants are high-risk medical devices, and material properties are essential parameters for preclinical evaluation to ensure their safety after implantation.

The basic conditions for effectiveness. The GB 4234 series of standards, "Metallic Materials for Surgical Implants," aims to regulate the performance requirements of metallic materials used in surgical implants.

The summation test method is proposed to consist of the following parts.

---Part 1. Forged Stainless Steel. The purpose is to standardize the performance requirements and test methods for forged stainless steel materials used in surgical implants.

---Part 2. Pure Titanium. The purpose is to standardize the performance requirements and test methods for pure titanium materials used in surgical implants.

---Part 3. Forged Titanium-6 Aluminum-4 Vanadium Alloy. The purpose is to standardize the properties of forged titanium-6 aluminum-4 vanadium alloy materials for surgical implants.

Requirements and testing methods.

---Part 4. Cast Cobalt-Chromium-Molybdenum Alloys. The purpose is to standardize the performance requirements of cast cobalt-chromium-molybdenum alloy materials for surgical implants.

and experimental methods.

---Part 5. Forged Cobalt-Chromium-Tungsten-Nickel Alloys. The purpose is to standardize the properties of forged cobalt-chromium-tungsten-nickel alloy materials for surgical implants.

Requirements and testing methods.

---Part 6. Forged Cobalt-Nickel-Chromium-Molybdenum Alloys. The purpose is to standardize the properties of forged cobalt-nickel-chromium-molybdenum alloy materials for surgical implants.

Requirements and testing methods.

---Part 7. Malleable and Cold-Workable Cobalt-Chromium-Nickel-Molybdenum-Iron Alloys. The purpose is to standardize malleable and cold-workable alloys for surgical implants.

Performance requirements and test methods for cobalt-chromium-nickel-molybdenum-iron alloy materials.

---Part 9. Forged High-Nitrogen Stainless Steel. The purpose is to standardize the performance requirements of forged high-nitrogen stainless steel materials for surgical implants.

Experimental methods.

---Part 11. Forged Titanium-6 Aluminum-7 Niobium Alloy. The purpose is to standardize forged titanium-6 aluminum-7 niobium alloy materials for surgical implants.

Performance requirements and test methods.

---Part 12. Forged Cobalt-Chromium-Molybdenum Alloys. The purpose is to standardize the

performance requirements of forged cobalt-chromium-molybdenum alloy materials for surgical implants.

Summation test method.

Currently, no known surgical implant material has been proven to be completely free of toxic side effects in humans. However, the materials discussed in this document...

Long-term clinical use has shown that, when applied appropriately, the expected level of biological response is acceptable. However, this document concerns...

Raw materials, rather than finished medical devices, are used; the design and manufacture of devices may affect biological responses.

Surgical implant metal materials

Part 11. Forged Titanium-6 Aluminum-7 Niobium Alloy

1 Scope

This document specifies the performance requirements for forged titanium-6 aluminum-7 niobium alloys for surgical implants and describes the corresponding test methods.

This document applies to the testing and evaluation of forged titanium-6 aluminum-7 niobium alloys for surgical implants.

Note. This document can be used as a reference for the preparation of titanium-6 aluminum-7 niobium alloys for surgical implants using other plastic processing techniques such as rolling, extrusion, and drawing.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB/T 228.1 Metallic materials-Tensile testing-Part 1. Tests at room temperature (GB/T 228.1-2021, ISO 6892-1)

2019, MOD)

YY/T 0512-2009 Classification of microstructures of alpha-beta titanium alloy rods for surgical implants (ISO.20160.

2006, IDT)