

ICS 11.040.40

CCS C 35



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

GB 4234.3-2024

**Implants for surgery - Metallic materials - Part 3: Wrought
titanium 6-aluminum 4-vanadium alloy**

(English Translation)

Issued on: October 28, 2024

Implemented on: November 1, 2026

**Issued by: State Administration for Market Regulation, China National
Standardization Administration**

Table of Contents

Preface	
Introduction	
1 Scope	1
2 Normative references	1
3 Terms and Definitions	1
4 Chemical composition	1
5 Microstructure	2
6 Mechanical properties	2
7 Test methods	3
Appendix A (Informative) Typical metallographic photographs of the microstructure of titanium alloys in the alpha beta phase region	4
Appendix B (Informative) Mechanical properties relationship between ISO and ASTM standards for Ti-6Al-4V titanium alloy materials for surgical implants	5
References	6

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1. Structure and drafting rules for standardization documents"

Drafting.

This document is Part 3 of GB 4234 "Metallic materials for surgical implants". GB 4234 has been published in the following parts.

- Part 1. Forged stainless steel;
- Part 2. Pure titanium;
- Part 3. Wrought titanium-6 aluminium-4 vanadium alloy;
- Part 4. Cast cobalt-chromium-molybdenum alloys;
- Part 7. Forgeable and cold worked cobalt-chromium-nickel-molybdenum-iron alloys;
- Part 9. Forged high nitrogen stainless steel;
- Part 12. Wrought cobalt-chromium-molybdenum alloys.

This document modifies ISO 5832-3:2021 "Metallic materials for surgical implants - Part 3. Wrought titanium-6 aluminium-4 vanadium alloy".

The technical differences between this document and ISO 5832-3:2021 and their reasons are as follows.

- ISO 6892-1 (see Chapter 7) was replaced by the normative reference GB/T 228.1 to adapt to my country's technical conditions;
- ISO 7438 (see Chapter 7) was replaced by the normative reference GB/T 232 to adapt to my country's technical conditions;
- Replaced ISO.20160 (see Chapter 5 and Chapter 7) with the normative reference YY/T 0512 to adapt to my country's technical conditions;
- Added GB/T 4698 (all parts) (see Chapter 7).

Introduction

Implants are high-risk medical devices, and their material properties are essential parameters for preclinical evaluation to ensure the safety of implants after implantation in the human body.

GB 4234 "Metallic Materials for Surgical Implants" series of standards aims to standardize the performance of metallic materials for surgical implants.

The requirements and test methods are intended to consist of the following parts.

- Part 1. Wrought stainless steel. The purpose is to standardize the performance requirements and test methods of wrought stainless steel materials for surgical implants.
- Part 2. Pure titanium. The purpose is to standardize the performance requirements and test methods of pure titanium materials for surgical implants.
- Part 3. Wrought titanium-6 aluminum-4 vanadium alloy. The purpose is to standardize the properties of wrought titanium-6 aluminum-4 vanadium alloy materials for surgical implants Requirements and test methods.
- Part 4. Cast cobalt-chromium-molybdenum alloy. The purpose is to specify the performance requirements of cast cobalt-chromium-molybdenum alloy materials for surgical implants and test methods.
- Part 5. Wrought cobalt-chromium-tungsten-nickel alloy. The purpose is to standardize the properties of wrought cobalt-chromium-tungsten-nickel alloy materials for surgical implants. Requirements and test methods.
- Part 6. Wrought cobalt-nickel-chromium-molybdenum alloy. The purpose is to standardize the properties of wrought cobalt-nickel-chromium-molybdenum alloy materials for surgical implants.

Requirements and test methods.

--- Part 7. Forgeable and cold worked cobalt-chromium-nickel-molybdenum-iron alloys. The purpose is to specify forgeable and cold worked cobalt-chromium-nickel-molybdenum-iron 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 and

Test method.

--- Part 11. Wrought titanium-6 aluminum-7 niobium alloy. The purpose is to standardize the properties of wrought titanium-6 aluminum-7 niobium alloy materials for surgical implants.

Requirements and test methods.

--- Part 12. Wrought cobalt-chromium-molybdenum alloys. The purpose is to specify the performance requirements of wrought cobalt-chromium-molybdenum alloy materials for surgical implants.

Summation test method.

There is no known surgical implant material that has been proven to be completely non-toxic to the human body. However, the materials covered in this document

Long-term clinical use has shown that the expected level of biological response is acceptable if used appropriately.

It is a raw material rather than a finished medical device. The design and manufacture of the device may affect the biological response.

Surgical implant metal materials

Part 3. Wrought titanium-6 aluminium-4 vanadium alloys

1 Scope

This document specifies the property requirements for wrought titanium-6 aluminum-4 vanadium (Ti-6Al-4V) alloys used in the manufacture of surgical implants and describes the corresponding

Test method.

This document applies to the test evaluation of wrought Ti-6Al-4V alloy for the manufacture of surgical implants.

Note: The mechanical properties of the samples taken from the finished devices made of this alloy

raw material may not necessarily comply with the requirements of this document.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to

This document.

GB/T 228.1 Tensile tests on metallic materials - Part 1. Test methods at room temperature (GB/T 228.1-2021, ISO 6892-1.

2019, MOD)

GB/T 232 Metallic materials bending test method (GB/T 232-2024, ISO 7438.2020, MOD)

GB/T 4698 (all parts) Chemical analysis methods for titanium sponge, titanium and titanium alloys

YY/T 0512 Surgical implant metal materials alpha beta titanium alloy rod microstructure classification (YY/T 0512-2009,

ISO.20160.2006, IDT)

3 Terms and definitions

The terms and definitions defined in GB/T 228.1 and the following apply to this document.

3.1

Original gauge length original gauge length

L₀

At any time before the force is applied at room temperature, it is used to measure the length of the parallel portion of the specimen elongation.

[Source. GB/T 228.1-2021, 3.1.1, modified]

4 Chemical composition

When a representative alloy sample is used for smelting analysis according to the method specified in Chapter 7, its chemical composition shall conform to that in Table 1.

Regulation.

Note 1: Except for the hydrogen content which is tested on the finished product, the analysis results