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

GB 4234.2-2024

**Implants for surgery - Metallic materials - Part 2: Unalloyed
titanium**

(English Translation)

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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 2 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 is modified to adopt ISO 5832-2:2018 "Metallic materials for surgical implants - Part 2. Pure titanium".

This document has the following structural adjustments compared to ISO 5832-2:2018.

- Note 1 in Table 2 corresponds to paragraph 2 of Chapter 1 of ISO 5832-2:2018;
- Note 2 in Table 2 corresponds to the note in Chapter 1 of ISO 5832-2:2018;
- Footnote d in Table 2 corresponds to footnote e in Table 2 in ISO 5832-2:2018.

The technical differences between this document and ISO 5832-2:2018 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;
- Added GB/T 4698 (all parts) (see Chapter 7);
- Added GB/T 6394 (see Chapter 7);
- The test method for the parameter "grain size" in Table 3 has been increased from GB/T 6394 (see Chapter 7) to adapt to my country's technical conditions, and increased Operability.

The following editorial changes were made to this document.

- Deleted footnote d in Table 2 of ISO 5832-2:2018.

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 aluminium-7 niobium alloy. The purpose is to specify the wrought titanium-6 aluminium-7 niobium alloy material for surgical implants.

Performance 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 applications have shown that if applied appropriately, the expected level of biological response is acceptable.

Surgical implant metal materials

Part 2. Pure titanium

1 Scope

This document specifies the performance requirements for pure titanium for surgical implants and describes the corresponding test methods.

This document applies to the testing and evaluation of pure titanium for surgical implants.

2 Normative references

The contents of the following documents constitute the 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

GB/T 6394 Determination of average grain size of metals
size)

GrainSize)

3 Terms and definitions

There are no terms or definitions that require definition in this document.

4 Chemical composition

The chemical composition of the alloy shall be in accordance with the method specified in Chapter 7.

The chemical composition can be analyzed by ingot analysis, and the hydrogen element should be determined after the final heat treatment and pickling procedures.

Table 1 Chemical composition

element

Chemical composition (mass fraction)

1ELI Level 1 Level 2 Level 3 Level 4A and Level 4B

Nitrogen (N) ≤ 0.012 ≤ 0.03 ≤ 0.03 ≤ 0.05 ≤ 0.05

Carbon (C) ≤ 0.03 ≤ 0.08 ≤ 0.08 ≤ 0.08 ≤ 0.08