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

**GB 4234.12-2024**

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**Implants for surgery - Metallic materials - Part 12: Wrought  
cobalt-chromium-molybdenum alloy**

**(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 12 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 5832-12:2019 "Metallic materials for surgical implants - Part 12. Wrought cobalt-chromium-molybdenum alloys".

The technical differences between this document and ISO 5832-12:2019 and their reasons are as follows.

- ISO 6892-1 (see Chapter 7) has been replaced by the normative reference GB/T 228.1 to adapt to my country's technical conditions and improve the reliability of the product.

Operability;

--- ISO 643 (see Chapter 7) has been replaced by the normative reference GB/T 6394 to adapt to my country's technical conditions and improve operability.

Acting nature.

The following editorial changes were made to this document.

--- Move "Note 1" in Chapter 1 of ISO 5832-12:2019 to "Note" in Chapter 6.

## 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 regulate the properties of metallic materials for surgical implants.

The performance 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 12. Wrought cobalt-chromium-molybdenum alloys

## 1 Scope

This document specifies the requirements for two wrought Cobalt-28Chromium-6Molybdenum alloys for use in surgical implants.

This document applies to press-worked rods and wires.

**Note:** High carbon alloys produce a distinct carbide distribution structure that can be adjusted during the production of the bar or during the subsequent heat treatment of the finished product.

The distribution of substances is outside the scope 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 6394 Determination of average grain size of metals

### 3 Terms and definitions

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

The terminology databases used for standardization maintained by ISO and IEC are located at.

### 4 Chemical composition

Conduct smelting analysis on representative alloy samples according to the method specified in Chapter 7, and their chemical composition shall conform to the requirements of Table 1.

Table 1 Chemical composition

element

Chemical composition

%(mass fraction)

Alloy 1 (low carbon) Alloy 2 (high carbon)

Chromium (Cr) 26.0~30.0 26.0~30.0

Molybdenum (Mo) 5.0~7.0 5.0~7.0

Iron (Fe)  $\leq 0.75$   $\leq 0.75$

Manganese (Mn)  $\leq 1.0$   $\leq 1.0$

END: Draft Version (GB 4234.12-2024)