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

GB 4234.7-2024

**Implants for surgery - Metallic materials - Part 7: Forgeable and
cold-formed cobalt-chromium-nickel-molybdenum-iron 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 7 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 5832-7:2024 "Metallic materials for surgical implants - Part 7. Wrought and cold worked cobalt-chromium-nickel-

"Molybdenum-Iron Alloy".

This document has the following structural adjustments compared to ISO 5832-7:2024.

- The description of the mechanical properties of the finished specimens in Table 3 corresponds to Chapter 1 "Notes" of ISO 5832-7:2024.

The technical differences between this document and ISO 5832-7:2024 and their reasons are as follows.

--- ISO 6892-1 (see Chapters 3 and 7) has been replaced by the normative reference GB/T 228.1 to adapt to the technical requirements of my country.

parts, increasing operability;

--- ISO 7438 (see Chapter 7) has been replaced by the normative reference GB/T 10561 to adapt to my country's technical conditions and increase operability.

Sex;

--- Added GB/T 223 (all parts) (see Chapter 7);

--- Added GB/T 6394 and ASTM E112 (see Chapter 7);

--- The test method for the parameter "grain size" in Table 4 has been increased from GB/T 6394 (see Chapter 7) to adapt to my country's technical conditions.

Operability.

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.

The materials have been shown in long-term clinical use to produce an acceptable level of expected biological response 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.

Metallic materials for surgical implants Part 7. Wrought and
Cold worked cobalt-chromium-nickel-molybdenum-iron alloy

1 Scope

This document specifies the property requirements for wrought and cold worked cobalt-chromium-nickel-molybdenum-iron alloys for surgical implants and describes the

appropriate test procedures.

method.

This document applies to the test evaluation of wrought and cold worked cobalt-chromium-nickel-molybdenum-iron alloys for surgical implants.

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 223 (all parts) Iron, steel and alloys

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

GB/T 10561 Determination of non-metallic inclusions in steel - Grading chart microscopic examination method (GB/T 10561-2023,

ISO 4967.2013, MOD)

apparent grain size)

Grain Size)

3 Terms and definitions

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

4 Chemical composition

The alloy shall be melted and analyzed according to the method specified in Chapter 7. Its chemical composition shall conform to the requirements of Table 1.

The chemical composition of the samples obtained from the products should also conform to the requirements of Table 1.

Table 1 Chemical composition

element