

ICS 11.040.40

CCS H40



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

GB 4234.1-2017

**Implants for surgery-Metallic materials-Part 1: Wrought
stainless steel**

外科植入物 金属材料 第1部分：锻造不锈钢

(English Translation)

Issued on: December 29, 2017

Implemented on: July 1, 2019

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine of the People's Republic of China;
Standardization Administration of China**

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Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020

Directives for standardization - Part 1. Rules for the structure and drafting of standardizing documents.

This document is Part 1 of GB 4234 Implants for surgery - Metallic materials. GB 4234 has already published the following parts.

- Part 1. Wrought stainless steel;
- Part 2. Unalloyed titanium;
- Part 3. Wrought titanium 6-aluminum 4-vanadium alloy;
- Part 4. Cobalt-chromium-molybdenum casting alloy;
- Part 7. Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy;
- Part 9. Wrought high nitrogen stainless steel;
- Part 11. Wrought titanium 6-aluminium 7-niobium alloy;
- Part 12. Wrought cobalt-chromium-molybdenum alloy.

This document replaces GB 4234.1-2017 Implants for surgery - Metallic materials - Part 1. Wrought stainless steel. Compared with GB 4234.1-2017, apart from structural

adjustments and editorial changes, the main technical changes are as follows.

- The chapter "Terms and definitions" has been added (see Chapter 3);
- The requirements for silicon (Si) in the chemical composition have been changed, and the requirements for cobalt (Co) have been added (see Table 1; see Table 1 in the 2017 edition);
- The requirements for the mechanical properties of the wire have been changed (see Table 4; see Table 4 in the 2017 edition);
- The requirements for gauge length of mechanical properties have been changed (see 6.3; see 5.3 in the 2017 edition);
- The test methods for carbon (C), silicon (Si), manganese (Mn), sulfur (S), and phosphorus (P) have been changed (see Table 6; see Table 6 in the 2017 edition).

Implants for surgery - Metallic materials - Part 1. Wrought
stainless steel

1 Scope

This document specifies the performance requirements for wrought stainless steel used in surgical implants and describes the corresponding test methods.

This document applies to the testing and evaluation of wrought stainless steel materials used in surgical implants.

NOTE: The alloys described in this document correspond to alloys with UNS number S31673 in ASTM

F138/ASTM F139.

2 Normative references

The provisions of the following documents constitute the essential clauses of this document through normative references in this text. Among them, for any dated reference, only the version corresponding to that date applies to this document; for any undated reference, the latest version (including all amendments) applies to this document.

GB/T 223(all parts) Iron, steel and alloy

GB/T 228.1-2021 Metallic materials - Tensile testing - Part 1. Method of test at room temperature (ISO 6892-1.2019, MOD)

NOTE: The content referenced from GB/T 228.1-2021 is not technically different from the content referenced from ISO 6892-1.2019.

GB/T 2975 Steel and steel products - Location and preparation of samples and test pieces for mechanical testing (GB/T 2975-2018, ISO 377.2017, MOD)

GB/T 6394 Determination of estimating the average grain size of metal

GB/T 10561-2023 Determination of content of nonmetallic inclusions in steel - Micrographic method using standard diagrams (ISO 4967.2013, MOD)

GB/T 17505 Steel and steel products - General technical delivery requirements (GB/T 17505-2016, ISO 404.2013, MOD)

ISO 643 Steel - Micrographic determination of the apparent grain size

3 Terms and definitions

For the purposes of this document, the terms and definitions given in GB/T 228.1-2021 apply.

4.1 Specimen

The selection of specimens for analysis shall comply with the provisions of GB/T 2975.

4.2 Melting analysis

The melting analysis of steel shall be performed according to the methods specified in Chapter 7, and its chemical composition shall conform to the provisions of Table 1.

The calculation result (C value) of chromium (Cr) content and molybdenum (Mo) content obtained by formula (1) shall not be less than 26.

where

wMo -- the content of molybdenum (Mo), expressed as a mass fraction (%);

wCr -- the content of chromium (Cr), expressed as a mass fraction (%).

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