

Translated English of Chinese Standard: GB4234.1-2017

[www.ChineseStandard.net](http://www.ChineseStandard.net) → Buy True-PDF → Auto-delivery.

[Sales@ChineseStandard.net](mailto:Sales@ChineseStandard.net)

# GB

NATIONAL STANDARD OF THE  
PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.40

H 40

## GB 4234.1-2017

Replacing GB 4234-2003

---

**Implants for surgery - Metallic materials –**

**Part 1: Wrought stainless steel**

(ISO 5832-1:2007, MOD)

外科植入物 金属材料

第 1 部分: 锻造不锈钢

**Issued on: December 29, 2017**

**Implemented on: July 1, 2019**

**Issued by: General Administration of Quality Supervision, Inspection and Quarantine;**

**Standardization Administration Committee.**

---

## Table of Contents

Foreword.....	3
1 Scope .....	6
2 Normative references .....	6
3 Chemical composition .....	7
4 Microstructure in the fully annealed condition.....	8
5 Mechanical properties .....	8
6 Test methods .....	9
Bibliography .....	11

## Foreword

All technical content of this Part is mandatory.

"Implants for surgery - Metallic materials" is expected to divide into 14 parts:

- Part 1: Wrought stainless steel;
- Part 2: Pure titanium;
- Part 3: Forged titanium 6 aluminum 4 vanadium alloy;
- Part 4: Cast cobalt-chromium-molybdenum alloy;
- Part 5: Forged cobalt-chromium-tungsten-nickel alloy;
- Part 6: Forged cobalt-nickel-chromium-molybdenum alloy;
- Part 7: Wrought and cold worked cobalt-chromium-nickel-molybdenum-iron alloy;
- Part 8: Forged cobalt-nickel-chromium-molybdenum-tungsten-iron alloy;
- Part 9: Forged high nitrogen stainless steel;
- Part 10: (preserved);
- Part 11: Forged titanium-6 aluminum-7 thallium alloy;
- Part 12: Forged cobalt-chromium-molybdenum alloy;
- Part 13: (preserved);
- Part 14: Forged titanium 15 molybdenum 5 zirconium 3 aluminum alloy.

This Part is Part 1 of "Implants for surgery - Metallic materials".

This Part was drafted in accordance with the rules given in GB/T 1.1-2009.

This Part replaces GB 4234-2003 "Stainless steel for surgical implants". Compared with GB 4234-2003, in addition to the editorial modifications, the main technical changes are as follows:

- deleted the order content, the contents of classification, size, shape, weight and allowable deviation, inspection rules, packaging, marks and quality certificate (Clause 3, Clause 4, Clause 5, Clause 8, Clause 9 of Edition 2003);
- deleted the contents of smelting method, delivery status, surface quality,

special requirements (6.2, 6.3, 6.6, 6.7 of Edition 2003);

- deleted the contents of chemical composition of which the designation is 00Cr18Ni15Mo3N as well as corresponding contents of mechanical properties (6.1.1, 6.4.1, 6.4.2, 6.4.3 of Edition 2003);
- modified the chemical composition of molybdenum (Mo) (see Table 1 of this Edition, Table 1 of Edition 2003);
- modified the mechanical properties of bars (see Table 3 of this Edition, Table 2 of Edition 2003);
- modified the mechanical properties of strip and sheet (see Table 5 of this Edition, Table 4 of Edition 2003);
- deleted the contents of Annex A, Annex B, Annex C (Annex A, Annex B and Annex C of Edition 2003).

NOTE: This Part seeks to be consistent with international standards to the greatest extent as possible. It deleted the contents that are suitable for order contract in Edition 2003.

This Part uses redrafting method to modify and adopt ISO 5832-1:2007 "Implants for surgery - Metallic materials - Part 1: Wrought stainless steel" and Amendment 1 issued in 2008.

Compared with ISO 5832-1:2007, the main differences in this Part are as follows:

- for the normative references, this Part made adjustments with technical differences to meet the technical conditions in China; the adjustments are centrally reflected in Clause 2 "Normative References", as follows:
  - replaced ISO 6892 with GB/T 228.1 whose modification used International standards;
  - replaced ISO 377 with GB/T 2975 whose modification used International standards;
  - replaced ISO 404 with GB/T 17505 whose modification used International standards.
- replaced the description of 5.3 "Gauge length" in ISO 5832-1:2007 with GB/T 228.1, so as to facilitate the standard user in China.

This Part made the following editorial modifications:

- made editorial modifications to the description methods of "specified non-proportional extension strength" and "elongation after fracture" in Table 3;

# Implants for surgery - Metallic materials -

## Part 1: Wrought stainless steel

### 1 Scope

This part of "Implants for surgery - Metallic materials" specifies the characteristics of, and corresponding test methods for wrought stainless steel for use in the manufacture of surgical implants.

This Part is applicable to wrought stainless steel for use in the manufacture of surgical implants.

**NOTE 1** The mechanical properties of a sample obtained from a finished product made of this alloy can differ from those specified in this Part.

**NOTE 2** The alloy described in this Part corresponds to UNS S31673 referred to in ASTM F 138 <sup>[1]</sup>/ASTM F 139 <sup>[2]</sup> and to alloy code 1.4441 given in the withdrawn DIN 17443 <sup>[3]</sup>.

### 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 228.1, *Metallic materials - Tensile testing - Part 1 : Method of test at room temperature* (GB/T 228.1-2010, ISO 6892-1: 2009, MOD)

GB/T 2975, *Steel and Steel Products - Location and Preparation of Test Pieces for Mechanical Testing* (GB/T 2975-1998, eqv ISO 377: 1997)

GB/T 10561-2005, *Steel - Determination of Content of Nonmetallic Inclusions - Micrographic Method Using Standards Diagrams* (ISO 4967:1998, IDT)

GB/T 17505, *Steel and steel products General technical delivery requirements* (GB/T 17505-2016, ISO 404:2013, MOD)

ISO 437, *Steel and cast iron - Determination of total carbon content - Combustion gravimetric method*

ISO 439, *Steel and iron - Determination of total silicon content - Gravimetric*