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

GB 4234.9-2023

**Implants for surgery - Metallic materials - Part 9: Wrought high
nitrogen stainless steel
(English Translation)**

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Foreword

This document complies with the provisions of GB/T 1:1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents"

Drafting:

This document is Part 9 of GB 4234 "Metal Materials for Surgical Implants": GB 4234 has released the following parts:

- Part 1: Forged stainless steel;
- Part 4: Cast cobalt-chromium-molybdenum alloys;
- Part 9: Forged high-nitrogen stainless steel:

This document is modified to adopt ISO 5832-9:2019 "Metallic Materials for Surgical Implants Part 9: Forged High-Nitrogen Stainless Steel":

The technical differences between this document and ISO 5832-9:2019 and their reasons are as follows:

--- Added to "Scope" "This document is applicable to the testing and evaluation of forged high-nitrogen stainless steel materials for the manufacture of surgical implants:" (See Section 1

chapter);

---Replaced ISO 6892-1 (see Table 6) with GB/T 228:1 to adapt to my country's national

conditions;

---Replaced ISO 377 (see 4:1 and 7:1) with GB/T 2975 to adapt to my country's national conditions;

---Replaced ISO 3651-2 (see Table 6) with GB/T 4334-2020 to adapt to my country's national conditions;

---Replaced ISO 4967 (see Table 6) with GB/T 10561-2023 to adapt to my country's national conditions;

---Replaced ISO 404:2013 (see 7:2) with GB/T 17505-2016 to adapt to my country's national conditions;

---Added reference to GB/T 6394 (see Table 6) to adapt to my country's technical conditions and increase operability:

Please note that some content in this document may be subject to patents: The publisher of this document assumes no responsibility for identifying patents:

Introduction

Implants are high-risk medical devices, and their material properties are necessary parameters for preclinical evaluation and to ensure the safety of the implant after implantation in the human body:

Basic conditions for full validity: The series of standards "Metal Materials for Surgical Implants" aims to standardize the performance requirements and

The test method is intended to consist of the following parts:

---Part 1: Forged stainless steel: The purpose is to standardize the performance requirements and test methods for forged 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: Forged titanium-6 aluminum-4 vanadium alloy: The purpose is to standardize the properties of forged titanium-6 aluminum-4 vanadium alloy materials for surgical implants:

Energy requirements and test methods:

---Part 4: Cast cobalt-chromium-molybdenum alloys: The purpose is to standardize the performance requirements for cast cobalt-chromium-molybdenum alloy materials for surgical implants:

and test methods:

---Part 5: Forged cobalt-chromium-tungsten-nickel alloys: The purpose is to standardize the properties of wrought cobalt-chromium-tungsten-nickel alloy materials for surgical implants:

Energy requirements and test methods:

---Part 6: Forged cobalt-nickel-chromium-molybdenum alloys: The purpose is to standardize the properties of wrought cobalt-nickel-chromium-molybdenum alloy materials for surgical implants:

Energy requirements and test methods:

---Part 7: Malleable and cold-workable cobalt-chromium-nickel-molybdenum-iron alloys: The purpose is to standardize the use of malleable and cold-worked materials 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 performance requirements of forged high-nitrogen stainless steel materials for surgical implants:

experiment method:

---Part 11: Forged titanium-6 aluminum-7 niobium alloy: The purpose is to standardize the quality of forged titanium-6 aluminum-7 niobium alloy materials for surgical implants:

Performance requirements and test methods:

---Part 12: Forged cobalt-chromium-molybdenum alloys: The purpose is to standardize the properties of wrought cobalt-chromium-molybdenum alloy materials for surgical implants:

Energy requirements and test methods:

None of the currently known surgical implant materials has been proven to be completely nontoxic to the human body: However, this document covers

The material has demonstrated in long-term clinical use that its expected level of biological response is acceptable if applied appropriately:

Surgical implant metal materials

Part 9: Forged high nitrogen stainless steel

1 Scope

This document specifies stainless steel with a nitrogen content of 0.25%~0.50% for surgical implants that require high strength and good corrosion resistance:

characteristics, and the corresponding test methods are described:

This document applies to the testing and evaluation of forged high-nitrogen stainless steel materials for the manufacture of surgical implants:

Note: For the requirements for stainless steel for other surgical implants, see GB 4234:1:

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text: Among them, the dated quotations

For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to

this document:

GB/T 228:1 Tensile testing of metallic materials Part 1: Room temperature test method (GB/T 228:1-2021, ISO 6892-1:

2019,MOD)

GB/T 2975 Sampling locations and sample preparation for mechanical property testing of steel and steel products (GB/T 2975-2018, ISO 377:

2017,MOD)

GB/T 4334-2020 Corrosion test method for austenitic and ferritic-austenitic (duplex) stainless steel intergranular corrosion of metals and alloys

Law (ISO 3651-1:1998; ISO 3651-2:1998, MOD)

GB/T 6394 Determination of average grain size of metals

GB/T 10561-2023 Standard rating chart microscopic examination method for determination of non-metallic inclusion content in steel (ISO 4967:2013,

MOD)

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

size)

3 Terms and definitions

There are no terms or definitions to be defined in this document:

4 chemical composition

4:1 Sample

The selection of samples for chemical analysis should comply with the provisions of GB/T 2975: