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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 4234.4-2019

Implants for surgery -- Metallic materials -- Part 4: Cobalt-chromium-molybdenum casting alloy

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Foreword

The entire technical content of this section is mandatory.

GB 4234 `` Metal Materials for Surgical Implants '' is expected to be divided into 14 parts.

--- Part 1. Forged 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 alloys;

--- Part 6. Forged cobalt-nickel-chromium-molybdenum alloy;

--- Part 7. Cobalt-chromium-nickel-molybdenum-iron alloys that can be forged and cold worked;

--- Part 8. Forged cobalt-nickel-chromium-molybdenum-tungsten-iron alloys;

--- Part 9. Forged high nitrogen stainless steel;

--- Part 10. (Reserved);

--- Part 11. Forged titanium-6 aluminum-7 niobium alloy;

--- Part 12. Forged cobalt-chromium-molybdenum alloy;

--- Part 13. (Reserved);

--- Part 14. Forged titanium 15 molybdenum 5 zirconium 3 aluminum alloy.

This part is Part 4 of GB 4234.

This section is drafted in accordance with the rules given in GB/T 1.1-2009.

This section replaces GB 17100-1997, Cast Cobalt Chromium-Molybdenum Alloy for Surgical Implants. Compared with GB 17100-1997, the main technology

The changes are as follows.

--- Revised the scope, normative references and test methods (see Chapter 1, Chapter 2 and Table 3, Chapter 1, Chapter 2 of the.1997 edition

Chapter and Chapter 4);

--- Removed alloy melting conditions, supply status, sample preparation process and casting conditions, inspection rules and the content of quality certificates (see

1997 version 3.1, 3.3, 3.4, Chapter 5, Chapter 6).

This part uses the redrafting method to modify and adopt ISO 5832-4..2014 "Surgery implant metallic materials-Part 4. Cast cobalt-

Chromium-Molybdenum Alloy.

The technical differences between this part and ISO 5832-4..2014 and their causes are as follows.

--- Regarding the normative reference documents, this section has made adjustments with technical differences to adapt to China's technical conditions and the situation of adjustment.

The situation is reflected in Chapter 2 "Regulatory Reference Documents", and the specific adjustments are as follows.

* ISO /6892-1 was replaced by GB/T 228.1 which adopted the international standard.

Please note that some elements of this document may involve patents. The issuer of this document is not responsible for identifying these patents.

This section is proposed and managed by the State Drug Administration.

This section was drafted. Tianjin Medical Device Quality Supervision and Inspection Center.

Introduction

None of the currently known surgical implant materials has been proven to be completely non-toxic to the human body. But the material covered in this section

It has been shown in long-term clinical applications that if the application is appropriate, its expected level of biological response is acceptable.

Surgical implant metal

Part 4. Casting of cobalt-chromium-molybdenum alloys

1 Scope

This part of GB 4234 specifies the characteristics and corresponding test methods of cast cobalt-chromium-molybdenum alloy for surgical implants.

This section applies to cast cobalt-chromium-molybdenum alloys for surgical implants.

Note. The mechanical properties of the sample taken from the finished product need not follow the provisions of this section.

2 Normative references

The following documents are essential for the application of this document. For dated references, only the dated version applies to this article

Pieces. For undated references, the latest version (including all amendments) applies to this document.

GB/T 228.1 Tensile test for metallic materials Part 1. Room temperature test method (GB/T 228.1-2010, ISO 6892-1.

(2009, MOD)

3 Chemical composition

According to the method specified in Chapter 5, the representative alloy samples are subjected to melting analysis, and their chemical composition should meet the requirements of Table 1.

See Table 1 for the content of main and residual elements in the cast cobalt-chromium-molybdenum alloy.

Table 1 Chemical composition

element

Chemical composition (mass fraction)

Chromium (Cr) 26.5 ~ 30.0

Molybdenum (Mo) 4.5 ~ 7.0

Nickel (Ni) <=1.0

Iron (Fe) <=1.0

Carbon (C)

Manganese (Mn) <=1.0

Silicon (Si) <=1.0

Cobalt (Co) matrix

4 Mechanical properties

Tested in accordance with the method specified in Chapter 5, its mechanical properties should meet the requirements of Table 2.

Table 2 Mechanical properties

Tensile strength Rm

MPa

Specified non-proportional elongation strength Rp0.2

MPa

Elongation after breaking aA

>=665 >=450 >=8

a Gage length = 5.65 S0 or 50mm, where S0 is the original cross-sectional area in square millimeters (mm2).

If any one of the samples does not meet the specified requirements or breaks outside the gauge range, two additional samples from the same batch must be used with

Method for testing. The alloy is considered qualified only if both samples meet the requirements.

The manufacturer may heat-treat the raw material again and re-inspect it according to the requirements of this section. In this case, all ministries

Parts should be heat treated in the same way.

5 Test method

The test methods used to determine the requirements of this section are shown in Table 3.

Representative samples for measuring mechanical properties shall be prepared in accordance with GB/T 228.1.

Table 3 Test methods

Requires related articles and test methods

Chemical Composition Chapter 3