

ICS 11.040.40
CCS C35

YY

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0117.3-2024

Replacing YY 0117.3-2005

**Implants for surgery - Forgings and castings for bone joint
prostheses - Part 3: Cobalt-chromium-molybdenum alloy
castings**

外科植入物 骨关节假体锻、铸件 第3部分：钴铬钼合金铸件

Issued on: July 8, 2024

Implemented on: July 20, 2027

Issued by: National Medical Products Administration

Table of Contents

- 1 Scope
- 1.0 Matrix
- 2 Normative references
- 3 Terms and definitions
- 4 Requirements
- 4.2 Mechanical properties

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 3 of YY 0117 "Surgical Implants - Bone and Joint Prosthesis Forgings and Castings". YY 0117 has been issued as follows part.

1. Ti6Al4V titanium alloy forgings;

--- Part 2: ZTi6Al4V titanium alloy castings;

3. Cobalt-chromium-molybdenum alloy castings. This document replaces YY 0117.3-2005 "Surgical Implants Bone and Joint Prosthesis Forgings and Castings Cobalt-Chromium-Molybdenum Alloy Castings" and Compared with YY 0117.3-2005, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

--- Deleted the notes on the Rockwell hardness reference values in Table 2 (see Table 2 of the.2005 edition);

--- Deleted the requirements for specific production process of castings (see 3.3 of the.2005 edition);

--- Clarified the requirements for the mechanical properties of castings and adjusted the applicable conditions for cast specimens in the corresponding clauses (see 4.2,.2005 edition 3.4);

--- Changed the surface quality requirements (see 4.3, 3.5 of the.2005 edition), added that there should be no discontinuity on the surface after grinding and repair welding Defective claims;

--- Changed the batching requirements and deleted the process requirements for "vacuum conditions" (see 6.1,

5.1 of the 2005 edition);

--- Changed the internal quality requirements. The allowable level of internal defects can meet the requirements of both the supplier and the buyer in accordance with Appendix A of YY/T 1565-2017 The limits of the recommended acceptable limits agreed upon in (see 4.4,

1 Scope

YY 0117.3 is Part 3 of the Chinese mandatory series on forgings and castings for joint prostheses, covering cobalt-chromium-molybdenum alloy castings. CoCrMo is the material of the bearing surfaces in hip and knee replacements, chosen for hardness and wear resistance, and casting is how the complex geometry of a femoral component is produced. Casting also introduces the defects that matter most in an implant: porosity, inclusions and grain structure that a machined bar would not have, and that determine fatigue life. The standard controls composition, structure and mechanical properties accordingly. The YY prefix without /T makes compliance compulsory in China. For an implant manufacturer or a foundry serving one, this is the material specification.

YY/T 0343 Liquid Penetrant Testing of Surgical Metal Implants

YY/T 1565-2017 Non-destructive testing of surgical implants - Radiographic testing of cast metal 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 test of metallic materials Part

GB/T 10610 Geometric Product Specification (GPS) Rules and methods for evaluating surface structure by surface structure profile method HB6573 Standard reference radiographs for investment steel castings HB20160 X-ray photography inspection

3 Terms and definitions

There are no terms or definitions that require definition in this document.

4 Requirements

4.1 Chemical composition Carry out the test according to the method described in 5.1. The chemical composition of the casting shall conform to the requirements of Table 1. Table

1 Chemical composition Elements C Cr Mo Ni Fe Mn Si Co Mass fraction/% ≤ 0.35
26.5~30.0 4.5~7.0 ≤ 1.0 ≤ 1.0 ≤ 1.0 $\leq$

4.2 Mechanical properties

4.2.1 Carry out the test according to the method described in 5.2. The mechanical properties of the casting shall meet the requirements of Table 2.