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

YY 0117.1-2024

Replacing YY 0117.1-2005

**Implants for surgery - Forgings and castings for bone joint
prostheses - Part 1: Ti6Al4V titanium alloy forgings**

外科植入物 骨关节假体锻、铸件 第1部分：Ti6Al4V钛合金锻件

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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 1 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 0117.1-2005 "Surgical Implant Bone and Joint Prosthesis Forgings and Castings Ti6Al4V Titanium Alloy Forgings" and Compared with YY 0117.1-2005, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

--- Deleted the processing requirements for raw materials (see

3.1.1 of the.2005 edition);

--- Changed the annealing specification (see note to 4.2,

3.2.2 of the.2005 edition);

--- Deleted the note on the Brinell hardness of forging surface as a reference (see Table 2 of the.2005 edition);

--- Changed the requirements for microstructure (see 4.6.3,

3.6.3 of the.2005 edition);

--- Changed the test method for chemical composition analysis and added other recognized analysis methods (existing ISO methods or national standards, Methods recommended by industry standards) (see 5.1,

4.1 of the 2005 edition);

1 Scope

YY 0117.1 is Part 1 of the Chinese mandatory series on forgings and castings for joint prostheses, covering Ti6Al4V titanium alloy forgings. Forging is how the load-bearing components of a hip or knee replacement are made when fatigue strength is the priority: working the metal aligns and refines the grain structure in a way casting cannot, and a hip stem that will see tens of millions of load cycles is a forging for that reason. The standard controls the alloy composition, the microstructure that the forging process must produce, and the mechanical properties that follow. The YY prefix without the /T suffix makes compliance compulsory in China. For an implant manufacturer or a forging supplier serving the Chinese market, this is the material specification.

YY/T 0512-2009 Classification of microstructure of alpha beta titanium alloy rods for 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 228.1 Tensile test of metallic materials Part

GB/T 4698 (all parts) Chemical analysis methods for titanium sponge, titanium and titanium alloys

GB/T 5168 Titanium and titanium alloy macrostructure inspection method

GB/T 10610 Geometric Product Specification (GPS) Rules and methods for evaluating surface structure by surface structure profile method

GB/T 11337 Flatness error detection

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 forgings shall conform to the requirements of Table 1. Other elements generally include. Sn, Mo, Cr, Mn, Zr, Ni, Cu, Si, Y (the alloy elements contained

in this grade should be removed). The following items may not be tested. When the purchaser deems it necessary, random inspection may be carried out. The results of random inspection shall comply with the provisions of Table 1. Table

1 Chemical composition of forgings Main ingredients Impurities Elements Al V Ti Fe CNHO
Other Elements Mass fraction/% 5.5~6.75 3.5~

4.5 Matrix $\leq 0.30 \leq 0.08 \leq 0.05 \leq 0.010 \leq$

0.20 Single sum $\leq 0.10 \leq$

0.40

Note. The hydrogen content is determined on the forgings in the supplied state.