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

YY/T 0966-2014

Implants for surgery - Metallic materials - Unalloyed tantalum

外科植入物 金属材料 纯钽

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. This standard uses the translation method identical with ISO 13782.1996 "surgical implants pure tantalum metal material" (English version). Correspondence between the consistency of the standards of international documents and normative references of the following documents.

--- GB/T 228.1-2010 tensile testing of metallic materials - Part 1. room temperature test methods (ISO 6892-1.2009, MOD) Please note that some of the content of this document may involve patents. Release mechanism of the present document does not assume responsibility for the identification of these patents. This standard was proposed by the China Food and Drug Administration. This standard by the national surgical implants and orthopedic instruments Standardization Technical Committee materials and orthopedic implants Technical Committee (SAC / TC110/SC1) centralized. This standard was drafted. Tianjin, the State Food and Drug Administration Medical Device Quality Supervision and Inspection Center, the State Food and Drug Pipe Authority for Medical Device Evaluation Center. The main drafters of this standard. Li Yuan, Fu Ruizhi, King Ming, Liu Bin, Dong Wenxing. Surgical implants of pure tantalum metal material

1 Scope

YY/T 0966 is the material standard for unalloyed tantalum used in surgical implants, and it applies to tantalum sheet, strip, rod and wire. It specifies the chemical composition the metal has to have, the microstructure it has to show, and the mechanical properties it has to deliver, together with the test methods that verify them. Tantalum is used where a highly biocompatible, corrosion-resistant and radiopaque metal is needed: cranial plates, markers, porous bone-ingrowth structures. Because an implant is only as good as the stock it is machined from, this is the document a Chinese reviewer expects the material certificate to cite. The standard carries Amendment 1 of 2023. For a foreign implant manufacturer it is the specification a Chinese distributor or contract manufacturer will ask the mill to certify against.

This standard specifies the characteristics of surgical implants pure tantalum sheet, strip,

rod, wire and the corresponding test methods.

Note. This standard specifies two grades of tantalum.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

ISO 6892-1.2009 Tensile testing of metallic materials - Part 1. room temperature test methods (Metalicmaterials-Tensile testing-Part 1. Methodoftestatroomtemperature)

ISO 643 steel microscopy determination of apparent grain size
(Steel-Micrographicdeterminationoftheapparentgrain size) Chemical composition

3 Accordance with the procedure prescribed in Chapter 6 of representative samples of alloy melting analysis, the chemical composition shall comply with the requirements in Table 1. all Element analysis method should be used ingot. Hydrogen analysis should be carried out after the final heat treatment and final surface treatment. Pure tantalum major elements and trace requirements in Table 1. Table

1 Chemical composition element Chemical composition (mass fraction) /% RO5200a
RO5400b Carbon ≤ 0.010 $\leq$

0.010 Oxygen ≤ 0.0150 $\leq$

0.030 Nitrogen ≤ 0.010 $\leq$

0.010 Hydrogen ≤ 0.0015 ≤ 0.0015 Niobium ≤ 0.100 $\leq$

0.100 Iron ≤ 0.010 $\leq$

0.010 Titanium ≤ 0.010 $\leq$

0.010 Tungsten ≤ 0.05 $\leq$

0.05 Molybdenum ≤ 0.020 $\leq$

0.020 Silicon ≤ 0.0050 ≤ 0.0050 Nickel ≤ 0.010 $\leq$

0.010 Tantalum Matrix matrix a electron beam or vacuum arc casting tantalum. b sintered tantalum.