भारतीय मानक

Indian Standard

IS 5347 (Part 17) : 2024
ISO 13782 : 2019

सर्जरी के लिए प्रत्यारोपण — धातु सामग्री — सर्जिकल प्रत्यारोपण अनुप्रयोगों के लिए शुद्ध टैंटलम

(पहला पुनरीक्षण)

Implants for Surgery — Metallic Materials — Unalloyed Tantalum for Surgical Implant Applications

(First Revision)

ICS 11.040.10

भारतीय मानक ब्यूरो
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Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02

NATIONAL FOREWORD

This Indian Standard (First Revision) which is identical to ISO 13782 : 2019 'Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Orthopaedic Instruments, Implants and Accessories Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 2002 and was identical to ISO 13782 : 1996 'Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications'. This revision has been brought out to align it with the latest version of ISO 13782 : 2019.

The text of ISO standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 643 Steels — Micrographic determination of the apparent grain size	IS 4748 : 2021/ISO 643 : 2019 Steel — Micrographic determination of the apparent grain size (*third revision*)	Identical
ISO 6892-1 Metallic materials — Tensile testing: Part 1 Method of test at room temperature	IS 1608 (Part 1) : 2022/ISO 6892-1 : 2019 Metallic materials — Tensile testing: Part 1 Method of test at room temperature (*fifth revision*)	Identical

The standard also makes a reference to the BIS certification marking of the product, details of which are given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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Introduction

No known surgical implant material has ever been shown to cause absolutely no adverse reaction in the human body. However, long-term clinical experience of the use of the material referred to in this document has shown that an acceptable level of biological response can be expected, when the material is used in appropriate applications.

Indian Standard

IMPLANTS FOR SURGERY — METALLIC MATERIALS — UNALLOYED TANTALUM FOR SURGICAL IMPLANT APPLICATIONS

(First Revision)

1 Scope

This document specifies the characteristics of, and corresponding test methods for, unalloyed tantalum sheet, rod and wire used in the manufacture of surgical implants.

NOTE 1 Provision is made for two grades of tantalum.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 643, *Steels — Micrographic determination of the apparent grain size*

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Chemical composition

The heat analysis of a representative sample of the materials when determined in accordance with Clause 7 shall be in conformity with the chemical composition specified in Table 1. Ingot analysis shall be used for reporting all chemical requirements.

The analysis of hydrogen shall be carried out after the final heat treatment and the final surface treatment.

Requirements for the major and minor elemental constituents for unalloyed tantalum are listed in Table 1.

Table 1 — Chemical composition

Element	Compositional limits % (m/m)	
	RO5200[a]	RO5400[b]
Carbon	0,010	0,010
Oxygen	0,015	0,030
Nitrogen	0,010	0,010
Hydrogen	0,001 5	0,001 5
Niobium	0,10	0,10
Iron	0,010	0,010
Titanium	0,010	0,010
Tungsten	0,050	0,050
Molybdenum	0,020	0,020
Silicon	0,005	0,005
Nickel	0,010	0,010
Tantalum	balance	balance

[a] Electron beam or vacuum-arc cast tantalum.

[b] Sintered tantalum.

5 Microstructure

The microscopic structure of the tantalum shall be uniform, and the grain size, determined in accordance with Clause 7, shall not be coarser than grain size No. 5.

6 Mechanical properties

The mechanical properties of the material, when tested in accordance with Clause 7, shall be in conformity with the values specified in Table 2.

If any of the test pieces fail within the gauge limits and do not meet specified requirements, two retest pieces shall be tested in the same manner, for each failed test piece. The alloy shall be deemed to be in conformity only if both additional test pieces meet the specified requirements.

If a test piece fails outside the gauge limits, the test is acceptable if the percentage elongation after fracture meets the requirements. If the percentage elongation after fracture does not meet requirements the test shall be discarded and a retest shall be performed.

If any of the retests fails to meet the appropriate requirements, the product represented shall be deemed not to be in conformity with this document. However, the manufacturer can, if desired, subject the material to heat treatment again and resubmit it for testing in accordance with this document.

Table 2 — Mechanical properties

Form	Condition	Thickness or diameter d mm	Tensile strength R_m MPa minimum	Yield strength or proof strength $R_{p0,2}$ MPa minimum	Percentage elongation after fracture A % minimum
Sheet and strip	Annealed	$0,13 \leq d \leq 0,26$	210	140	20
		$0,26 < d \leq 0,51$			25
		$> 0,51$			30
	Stress-relieved after cold work	$0,13 \leq d \leq 0,26$	380	240	5
		$> 0,26$			10
	Cold-worked	$\geq 0,13$	520	345	2
Rod and wire	Annealed	$0,25 \leq d \leq 0,38$	240	—	10
		$0,38 < d \leq 0,63$	240	—	15
		$0,63 < d \leq 3,14$	210	—	20
		$3,14 < d \leq 63,5$	170	140	25
	Cold-worked	all	480	345	1

7 Test methods

The test methods to be used in determining conformity with this document shall be those given in Table 3.

Representative test pieces for the determination of the tensile properties shall be prepared in accordance with ISO 6892-1.

Table 3 — Test methods

Parameter	Relevant clause	Test method
Chemical composition	4	Recognized analytical procedures (ISO methods where they exist)
Grain size	5	ISO 643
Mechanical properties	6	
Tensile strength		ISO 6892-1
Yield strength or proof strength		ISO 6892-1
Percentage elongation after fracture		ISO 6892-1

NATIONAL ANNEX A

(*National Foreword*)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product may be marked with the Standard Mark.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 2016 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

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Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the website-www.bis.gov.in or www.standardsbis.in.

This Indian Standard has been developed from Doc No.: MHD 02 (25874).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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