INTERNATIONAL STANDARD

ISO 13782

Second edition
2019-04

Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications

Implants chirurgicaux — Produits à base de métaux — Tantale non allié utilisé dans les implants chirurgicaux

Reference number
ISO 13782:2019(E)

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Published in Switzerland

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery,* Subcommittee SC 1, *Materials.*

This second edition cancels and replaces the first edition (ISO 13782:1996), which has been technically revised.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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.

Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications

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