INTERNATIONAL STANDARD

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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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 13782 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

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Introduction

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

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

1 Scope

This International Standard 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 standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6892:1984, *Metallic materials — Tensile testing.*

ISO 643:1983, *Steels — Micrographic determination of the ferritic or austenitic grain size.*

3 Chemical composition

The heat analysis of a representative sample of the material when determined in accordance with clause 6 shall comply 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 [1]	RO5400 [2]
Carbon	0,010	0,010
Oxygen	0,015 0	0,030
Nitrogen	0,010	0,010
Hydrogen	0,001 5	0,001 5
Niobium	0,100	0,100
Iron	0,010	0,010
Titanium	0,010	0,010
Tungsten	0,05	0,05
Molybdenum	0,020	0,020
Silicon	0,005 0	0,005 0
Nickel	0,010	0,010
Tantalum	balance	balance

1) Electron beam or vacuum-arc cast tantalum.
2) Sintered tantalum.

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4 Microstructure

The microscopic structure of the tantalum shall be uniform, and the grain size, determined in accordance with clause 6, shall not be coarser than grain size No. 5.

5 Mechanical properties

The mechanical properties of the material, when tested in accordance with clause 6, shall comply with the values specified in table 2.

6 Test methods

The test methods to be used in determining compliance with this International Standard 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.

Table 2 — Mechanical properties

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

Table 3 — Test methods

Parameter	Relevant clause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Grain size	4	ISO 643
Mechanical properties	5	
Tensile strength		ISO 6892
Proof stress of nonproportional elongation		ISO 6892
Percentage elongation		ISO 6892

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