Designation: F 560 – 04

Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)[1]

This standard is issued under the fixed designation F 560; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This standard has been approved for use by agencies of the Department of Defense.

1. Scope*

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for unalloyed tantalum plate, sheet, strip, rod, and wire used in the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard. The SI equivalents in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards:* [2]

B 364 Specification for Tantalum and Tantalum Alloy Ingots

B 365 Specification for Tantalum and Tantalum Alloy Rod and Wire

B 708 Specification for Tantalum and Tantalum Alloy Plate, Sheet, and Strip

E 8 Test Methods for Tension Testing of Metallic Materials

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

2.2 *American Society for Quality Control Standard:*[3]

ASQ C1 Specifications of General Requirements for a Quality Program

2.3 *ISO Standard:*[4]

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

3. General Requirements for Delivery

3.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications B 364, B 365, and B 708 shall apply.

3.2 In the case where a conflict exists between this specification and those listed in 2.1, 2.2, and 3.1, this specification shall take precedence.

TABLE 1 Chemical Requirements (Ingot)

Element	Compositions, max % mass/mass[A]	
	R05200[B]	R05400[C]
Carbon	0.010	0.010
Oxygen	0.015	0.03
Nitrogen	0.010	0.010
Hydrogen	0.0015	0.0015
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[D]	balance[D]

[A] For purposes of determining conformance with this specification, all compositional limits are absolute limits, as defined in Practice E 29.

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

[C] Sintered tantalum.

[D] The percentage of tantalum is determined by difference and need not be determined or certified.

4. Ordering Information

4.1 Inquiries and orders under this specification shall include the following information:

4.1.1 Quantity (weight or number of pieces),

4.1.2 ASTM designation,

4.1.3 Composition designation,

4.1.4 Form (strip, sheet, plate, rod, wire),

4.1.5 Condition (see 5.1),

4.1.6 Applicable dimensions, including size, thickness, width, and length (random, exact, multiples), or drawing number,

4.1.7 Special tests,

4.1.8 Special requirements, and

4.1.9 Mechanical properties (see 7.1).

[1] This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

Current edition approved Jan. 1, 2004. Published February 2004. Originally approved in 1978. Last previous edition approved in 1998 as F 560 – 98.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

***A Summary of Changes section appears at the end of this standard.**

TABLE 2 Mechanical Properties, Flat Mill Products

Condition	Thickness, in. (mm)	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength, (0.2% offset) min, psi (MPa)	Elongation[A] in 1 inch (25.4 mm), min,%
Cold worked	all	75 000 (517)	50 000 (345)	2
Stress relieved	0.0051 to 0.010 (0.13 to 0.26)	55 000 (379)	35 000 (241)	5
	over 0.010 to 0.020 (0.26 to 0.51)	55 000 (379)	35 000 (241)	10
	over 0.020(0.51)	55 000 (379)	35 000 (241)	10
Annealed	0.0051 to 0.010 (0.13 to 0.26)	30 000 (207)	20 000 (138)	20
	over 0.010 to 0.020 (0.26 to 0.51)	30 000 (207)	20 000 (138)	25
	over 0.020 (0.51)	30 000 (207)	20 000 (138)	30

[A] Elongation of material 0.063 in. (1.6 mm) or greater in diameter (D) or width (W) shall be measured using a gage length of 2 in. or 4D or 4W. The gage length must be reported with the test results. The method for determining elongation of material under 0.063 in. (1.6 mm) in diameter or thickness may be negotiated. Alternately, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser. (5.65 square root of So, where So is the original cross sectional area.)

TABLE 3 Mechanical Properties, Rod and Wire Products

Condition	Diameter, in. (mm)	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength, (0.2% offset)min, psi (MPa)	Elongation, min, %[A]
Cold Worked	all	70 000 (482)	50 000 (345)	1
Annealed	0.005 to 0.0099 (0.12 to 0.25)	35 000 (241)	. . .	8
	0.010 to 0.0149 (0.25 to 0.379)	35 000 (241)	. . .	10
	0.015 to 0.0249 (0.381 to 0.633)	35 000 (241)	. . .	15
	0.025 to 0.1249 (0.633 to 0.314)	30 000 (207)	. . .	20
	0.125 to 2.5 (3.2 to 64)	25 000 (172)	20 000 (138)	25

[A] Elongation of material 0.063 in. (1.6 mm) or greater in diameter (D) or width (W) shall be measured using a gage length of 2 in. or 4D or 4W. The gage length must be reported with the test results. The method for determining elongation of material under 0.063 in. (1.6 mm) in diameter or thickness may be negotiated. Alternately, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser. (5.65 square root of So, where So is the original cross sectional area.)

5. Manufacture

5.1 *Condition:*

5.1.1 Flat mill products material shall be supplied in the cold-worked, cold-worked and stress-relieved or annealed condition.

5.1.2 Rod and wire products shall be supplied in the annealed or cold worked condition.

6. Chemical Composition

6.1 The material shall conform to the chemical composition requirements in Table 1.

6.1.1 Requirements for the major and minor elemental constituents are listed in Table 1. Also listed are important residual elements. Analysis for elements not listed in Table 1 is not required to certify compliance with this specification.

7. Mechanical Properties

7.1 The material supplied under this specification shall conform to the mechanical property requirements in Tables 2 and 3. Mechanical properties for material in conditions other than those included in Tables 2 and 3 shall be specified by the purchaser.

7.2 Specimens for tension tests shall be machined and tested in accordance with Test Methods E 8. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in./min (mm/mm/min) through yield and then the crosshead speed may be increased so as to produce fracture in approximately one additional minute.

8. Certification

8.1 The supplier shall provide a certification that the material was tested in accordance with this specification and met all requirements. A report of the test results shall be furnished to the purchaser at the time of shipment.

9. Quality Program Requirements

9.1 The supplier shall maintain a quality program, such as defined in ASQ C1.

10. Keywords

10.1 metals (for surgical implants); orthopaedic medical devices; tantalum

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this specification is to characterize composition and properties to ensure consistency in the starting material used in the manufacture of medical devices.

X2. BIOCOMPATIBILITY

X2.1 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long term clinical experience has shown an acceptable level of biological response can be expected, if the material is used in appropriate applications.

X2.2 The material in this specification has been subjected to animal implant studies and has been shown to produce a well characterized level of biological response that is equal to or less than that produced by the reference material when tested by the procedures of Practice F 981 or the equivalent. This material has been used clinically for over a decade.[5]

[5] Black, Jonathan, " Biological Performance of Tantalum," Clinical Materials, Elsevier Science Limited, Vol 16, 1994, pp. 167–173.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F 560 – 98) that may impact the use of this standard. (Approved Jan. 1, 2004.)

(*1*) The UNS designation has been added to the title, residual element language has been included, the mechanical property tables have been modified, and Biocompatibility section has been added.
(*2*) Editorial corrections have been made in order to meet terminology and formatting guidelines established for implant material standards.
(*3*) Added ISO 6892 gage length for elongation determination to Tables 2 and 3. Added plate and strip forms and harmonized significant digits in Table 1, Chemical Composition, to coincide with the referenced specifications B 364, B 365, and B 708. Added Summary of Changes and moved X1.2 from Rationale to Summary of Changes. Corrected typographical errors in Tables 2 and 3. Harmonized diameter ranges in Table 3 with those from referenced Specification B 365.