Designation: F560 – 13$^{\varepsilon 1}$

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

This standard is issued under the fixed designation F560; 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.

ε[1] NOTE—The designation was corrected editorially in December 2013.

1. Scope*

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

1.2 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values of the two systems may result in non-conformance with this standard.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E8/E8M Test Methods for Tension Testing of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

IEEE/ASTM SI 10 American National Standard for Use of the International System of Units (SI): The Modern Metric System

2.2 *ISO Standards:*[3]

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems—Requirements

ISO 13782 Implants for Surgery—Metallic Materials—Unalloyed Tantalum for Surgical Implant Applications

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *lot*—all material produced from the same ingot or a single powder blend with the same cross section under the same conditions at essentially the same time.

3.1.2 *plate*—a flat product more than 4.75 mm [0.1875 in.] in thickness.

3.1.3 *bar*—material 3.15 to 63.5 mm [0.125 to 2.5 in.] in diameter in round, hexagonal, or octagonal cross section supplied in straight lengths.

3.1.4 *sheet*—a flat product 150 mm [6 in.] or more in width and from 0.13 to 4.75 mm [0.005 to 0.1875 in.] in thickness.

3.1.5 *strip*—a flat product less than 150 mm [6 in.] in width and from 0.13 to 4.75 mm [0.005 to 0.1875 in.] in thickness, may be supplied in coil.

3.1.6 *wire*—material up to 3.15 mm [0.124 in.] in diameter furnished in coils or on spools or reels.

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, alloy number, and date of issue,

4.1.3 Units to be used for certification—SI or inch-pound.

4.1.4 Composition designation (see 5.1)

4.1.5 Form (strip, sheet, plate, bar, wire) (see 3.1),

4.1.6 Condition (see 5.4),

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

4.1.8 Special tests,

4.1.9 Special requirements, and

4.1.10 Mechanical properties (if applicable for special conditions) (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.

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[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 National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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

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5. Materials and Manufacture

5.1 Material covered by this specification shall be made from vacuum-arc melted or electron-beam melted ingots (R05200) or powder-metallurgy consolidated (R05400) unalloyed tantalum.

5.2 The various tantalum mill products covered by this specification are formed with the conventional extrusion, forming, swaging, rolling, and drawing equipment normally available in metalworking plants.

5.3 *Finish*—The mill product may be furnished as descaled or pickled, abrasive blasted, chemically milled, ground, machined, peeled, polished, or as specified by the purchaser.

5.4 *Condition:*

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

5.4.2 Bar and wire products shall be supplied in the annealed or cold worked condition.

6. Chemical Requirements

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.

6.2 The ingot analysis shall be considered the chemical analysis for products supplied under this specification.

6.3 When requested by the purchaser at the time of purchase, the supplier shall furnish a report certifying the values of carbon, oxygen, nitrogen, and hydrogen as specified in Table 2 for each lot of material supplied.

7. Mechanical Properties

7.1 The material supplied under this specification shall conform to the mechanical property requirements in Tables 3 and 4. Mechanical properties for material in conditions other than those included in Tables 3 and 4 shall be specified by the purchaser.

TABLE 1 Chemical Requirements

Element	Compositions, max % mass/mass	
	R05200[A]	R05400[B]
Carbon	0.010	0.010
Oxygen	0.015	0.030
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[C]	balance[C]

[A] Electron-beam or vacuum-arc cast tantalum.
[B] Sintered tantalum.
[C] The percentage of tantalum is determined by difference and need not be determined or certified.

TABLE 2 Additional Chemical Requirements for Finished Product (When Specified by the Purchaser)

Element	Compositions, Maximum % mass/mass	
	R05200[A]	R05400[B]
Carbon	0.020	0.020
Oxygen	0.025	0.035
Nitrogen	0.010	0.010
Hydrogen	0.0015	0.0015

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

7.2 Specimens for tension tests shall be prepared and tested in accordance with Test Methods E8/E8M. Tensile properties shall be determined using a strain rate of 0.076 to 0.178 mm/mm/min [0.003 to 0.007 in./in./min] through yield and then the crosshead speed may be increased so as to produce fracture in approximately one additional minute.

7.3 *Number of Tests:*

7.3.1 *Bar and Wire*—Perform at least one tension for each lot. Should any of these test pieces not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test piece. The lot shall be considered in compliance only if all additional test pieces meet the specified requirements.

7.3.2 Tensile test results for which any specimen fractures outside the gage length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to Test Method E8/E8M, sections 7.11.4 and 7.11.5.

7.3.3 If either the elongation or the reduction of area is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements.

7.3.4 *Sheet, Strip, and Plate*—Perform at least one tension test for each lot. Tension property requirements apply in both the longitudinal and transverse directions. Tests in the transverse direction need be made only on product from which a specimen is not less than 200 mm [8.0 in.] in length for sheet and 64 mm [2.5 in.] in length for plate can be taken. Should any of these test pieces not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test piece. The lot shall be considered in compliance only if both additional test pieces meet the specified requirements.

8. Dimensions, Mass, and Permissible Variations

8.1 *Units of Measure:*

8.1.1 *Selection*—This specification requires that the purchaser select the units of measure (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order (PO), this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

8.1.1.1 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

8.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's purchase order

TABLE 3 Mechanical Properties, Flat Mill Products

Condition	Thickness, mm [in.]	Minimum Ultimate Tensile Strength, MPa [psi]	Minimum Yield Strength, (0.2% offset) MPa [psi]	Minimum Elongation[A] in 25 mm [1 in.] %
Cold worked	all	520 [75 000]	345 [50 000]	2
Stress relieved	0.13 to 0.26 [0.0051 to 0.01]	380 [55 000]	240 [35 000]	5
	over 0.26 [0.01]	380 [55 000]	240 [35 000]	10
Annealed	0.13 to 0.26 [0.0051 to 0.01]	210 [30 000]	140 [20 000]	20
	over 0.26 to 0.5 [0.010 to 0.020]	210 [30 000]	140 [20 000]	25
	over 0.51 [0.020]	210 [30 000]	140 [20 000]	30

[A] Elongation of material 1.6 mm [0.063 in.] or greater in diameter (D) or width (W) shall be measured using a gage length of 50 mm [2 in.] or 4D or 4W. The gage length shall be reported with the test results. The method for determining elongation of material under 1.6 mm [0.063 in.] in diameter or thickness may be negotiated. Alternately, a gage length corresponding to ISO 6892 (5.65 square root of So, where So is the original cross sectional area) may be used when agreed upon between the supplier and purchaser.

TABLE 4 Mechanical Properties, Bar and Wire Products

Condition	Diameter, mm [in.]	Minimum Ultimate Tensile Strength, MPa [psi]	Minimum Yield Strength, (0.2% offset) MPa [psi]	Minimum Elongation, %[A]
Cold Worked	all	480 [70 000]	345 [50 000]	1
Annealed	0.12 to under 0.25 [0.005 to 0.0099]	240 [35 000]	. . .	8
	0.25 to 0.38 [0.010 to 0.0149]	240 [35 000]	. . .	10
	over 0.38 to 0.63 [0.015 to 0.0249]	240 [35 000]	. . .	15
	over 0.63 to 3.14 [0.025 to 0.1249	210 [30 000]	. . .	20
	over 3.14 to 63.5 [0.125 to 2.5]	170 [25 000]	140 [20 000]	25

[A] Elongation of material 1.6 mm [0.063 in.] or greater in diameter (D) or width (W) shall be measured using a gage length of 50 mm [2 in.] or 4D or 4W. The gage length shall be reported with the test results. The method for determining elongation of material under 1.6 mm [0.063 in.] in diameter or thickness may be negotiated. Alternately, a gage length corresponding to ISO 6892 (5.65 square root of So, where So is the original cross sectional area) may be used when agreed upon between supplier and purchaser.

(PO), specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification.

8.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.

8.1.2 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A provides conversion tables and Annex B provides rules for conversion and significant digits.

9. Certification

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

10. Quality Program Requirements

10.1 The supplier shall maintain a quality program or quality management system, such as defined in ISO 9001.

11. Significance of Numerical Limits

11.1 The following applies to all specified limits in this specification: For purposes of determining conformance with this specification, an observed value or a calculated value shall be rounded "to the nearest unit" in the last right-hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E29.

12. Keywords

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

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary purpose of this specification is to characterize the chemical, mechanical, and metallurgical properties of wrought unalloyed tantalum to be used in the manufacture of surgical implants.

X1.2 The minimum mechanical properties specified ensure a baseline of strength and ductility for the highly stressed devices for which this alloy is typically used.

X1.3 Units of Measure

X1.3.1 *ASTM Policy*—ASTM is promoting the use of rationalized SI (metric) units in their standards. The F04.12 Committee has modified this specification to facilitate the transition by the medical materials industry to SI between 2012 and 2018. In the first phase of this transition, running to 2013, the specifications will be structured to allow the use of either SI or inch-pound units. The choice of primary units in each specification will be determined by the industry using the specification. The change to SI units during this period may be initiated by the purchaser through his purchase documentation. In the second phase of this transition, the specifications will be written with SI as the primary units. Harmonization with corresponding ISO documents should be considered when assigning the SI values.

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 F981 or the equivalent. This material has been used clinically for over a decade.[4]

[4] 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 (F560 – 08) that may impact the use of this standard. (Approved October 1, 2013.)

(1) Editorial corrections have been made to meet terminology and formatting guidelines established for implant material standards.
(2) Changed primary units from inch-pounds to SI and harmonized SI values with ISO 13782 where possible.
(3) Added wording to 1.2 and Section 4 and added Section 8 and X1.3 to support certifying in SI units.
(4) Added referenced to IEEE/ASTM SI 10 for use of SI units and reference to ISO 9001.
(5) Remedied the use of "rod" and "bar" to refer to the same product classification by changing all references of "rod" to "bar."
(6) In Table 3, stress relieved products "over 0.010 to 0.020 in." and "over 0.020 in." had the same properties. To eliminate the redundancy, replaced these two categories with a single "over 0.010 in." category.

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