Designation: F 560 – 98

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 requirements for unalloyed tantalum sheet, rod, and wire used for the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard. The metric equivalents of inch-pound units may be approximate.

2. Referenced Documents

2.1 *ASTM Standards:*

B 364 Specification for Tantalum and Tantalum Alloy Ingots[2]

B 365 Specification for Tantalum and Tantalum Alloy Rod and Wire[2]

B 708 Specification for Tantalum and Tantalum Alloy Plate, Sheet, and Strip[2]

E 8 Test Methods of Tension Testing of Metallic Materials[3]

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications[4]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[5]

2.2 *American Society for Quality Control Standard:*[6]

Cl Specifications of General Requirements for a Quality Program

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 and 2.2, this specification shall take precedence.

TABLE 1 Chemical Requirements (Ingot)

Element	Compositions, Maximum Weight Percent Allowed[A]	
	R05200[B]	R05400[C]
Carbon	0.010	0.010
Oxygen	0.0150	0.030
Nitrogen	0.010	0.010
Hydrogen	0.0015	0.0015
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	0.0050	0.0050
Nickel	0.010	0.010
Tantalum	balance	balance

[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.

4. Ordering Information

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

4.1.1 Quantity (weight and number of pieces),

4.1.2 ASTM designation,

4.1.3 Composition designation,

4.1.4 Form (sheet, rod, wire)

4.1.5 Condition (see 5.1)

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

4.1.7 Special tests, and

4.1.8 Special requirements.

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.

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices, and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

Current edition approved January 10, 1998. Published June 1998. Originally published as F 560 – 78. Last previous edition F 560 – 92.

[2] *Annual Book of ASTM Standards*, Vol 02.04.

[3] *Annual Book of ASTM Standards*, Vol 03.01.

[4] *Annual Book of ASTM Standards*, Vol 14.02.

[5] *Annual Book of ASTM Standards*, Vol 13.01.

[6] Available from American Society for Quality Control, 161 West Wisconsin Ave., Milwaukee, WI 53203.

TABLE 2 Mechanical Properties, Flat Mill Products

Condition	Thickness, in. (mm)	Ulimate Tensile Strength, min, psi (MPa)	Yeild Strength, (0.2% offset) min, psi (MPa)	Elongation 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

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 0.010 (0.12 to 0.25)	35 000 (241)	. . .	8
	over 0.010 to 0.015 (0.25 to 0.38)	35 000 (241)	. . .	10
	over 0.015 to 0.025 (0.38 to 0.64)	30 500 (241)	. . .	15
	over 0.025 to 0.125 (0.64 to 0.32)	30 000 (207)	. . .	20
	over 0.125 to 2.5 (3.2 to 64)	25 000 (172)	20 000 (138)	25

[A] Use 10-in. (254-mm) gage length for 0.050 in. (1.27-mm) diameter and below, 1 or 2 in. (25.4 or 50.8 mm) gage length for diameters over 0.050 in. (1.27 mm) to 0.125 in. (3.2 mm), and 1 in. (25.4mm) gage length for diameters over 0.125 in. (3.2 mm).

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 requirements as to chemical composition specified 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 shall conform to the appropriate requirements as to mechanical properties specified in Tables 2 and 3. Mechanical properties for material in conditions other than those included in Tables 2 and 3, shall be specified in the purchase order.

7.2 Perform tension testing in accordance with Test Methods E 8. Determine tensile properties using a strain rate of 0.003 to 0.007 in./in. (mm/mm)/min through the yield point, and then increase crosshead speed to produce fracture in approximately one minute.

8. Certification

8.1 The manufacturer's certification that the material was manufactured and tested in accordance with this specification together with a report of the test results shall be furnished at the time of shipment.

9. Quality Program Requirements

9.1 The producer shall maintain a quality program, such as that defined in ASQC Cl.

9.2 The manufacturer of surgical implants may audit the producer's quality program for conformance to the intent of ASQC C1, or other recognized program.

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.

X1.2 The USN designation has been added to the title, residual element language has been included, the mechanical properties tables have been modified, and Biocompatibility section has been added.

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.[7]

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