



Designation: F560 – 13<sup>ε1</sup>

# Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)<sup>1</sup>

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.

<sup>ε1</sup> 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*:<sup>2</sup>

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*:<sup>3</sup>

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems—Requirements

<sup>1</sup> 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 Oct. 1, 2013. Published November 2013. Originally approved in 1978. Last previous edition approved in 2008 as F560–08. DOI: 10.1520/F0560-13E01.

<sup>2</sup> 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.

<sup>3</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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).

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

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

| Element  | Compositions, Maximum % mass/mass |                     |
|----------|-----------------------------------|---------------------|
|          | R05200 <sup>A</sup>               | R05400 <sup>B</sup> |
| Carbon   | 0.020                             | 0.020               |
| Oxygen   | 0.025                             | 0.035               |
| Nitrogen | 0.010                             | 0.010               |
| Hydrogen | 0.0015                            | 0.0015              |

<sup>A</sup> Electron-beam or vacuum-arc cast tantalum.

<sup>B</sup> 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 1 Chemical Requirements**

| Element    | Compositions, max % mass/mass |                      |
|------------|-------------------------------|----------------------|
|            | R05200 <sup>A</sup>           | R05400 <sup>B</sup>  |
| 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 <sup>C</sup>          | balance <sup>C</sup> |

<sup>A</sup> Electron-beam or vacuum-arc cast tantalum.

<sup>B</sup> Sintered tantalum.

<sup>C</sup> The percentage of tantalum is determined by difference and need not be determined or certified.