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Standard Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150)[1]

This standard is issued under the fixed designation F 2066; 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.

1. Scope*

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought titanium-15 molybdenum alloy to be used in the manufacture of surgical implants (**1**).[2]

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:* [3]

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

E 112 Test Methods for Determining Average Grain Size

E 290 Test Methods for Bend Testing of Material for Ductility

E 1409 Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity/Infrared Detection Method

E 2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry

F 67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

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

F 1408 Practice for Subcutaneous Screening Test for Implant Materials

2.2 *Aerospace Material Specification:*

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys[4]

2.3 *ISO Standards:*[5]

ISO 6892 Metallic Materials — Tensile Testing

ISO 9001 Quality Management Systems

2.4 *American Society for Quality Standard:*

ASQ C1 Specification of General Requirements for a Quality Program[6]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *beta annealed*, *n*—the condition of the material that is obtained if, following the final hot-working or cold-working operation, the mill product is rapidly quenched, for example, by water quenching or pressurized helium gas quench, from a temperature above the beta transus of approximately 1382°F (750°C).

3.1.2 *beta transus*, *n*—the minimum temperature at which the alpha plus beta phase can transform to 100 % beta phase.

4. Product Classification

4.1 *Strip*—Any product under 0.1875 in. (4.76 mm) in thickness and under 24 in. (610 mm) wide.

4.2 *Sheet*—Any product under 0.1875 in. (4.76 mm) in thickness and 24 in. (610 mm) or more in width.

4.3 *Plate*—Any product 0.1875 in. (4.76 mm) thick and over and 10 in. (254 mm) wide and over, with widths greater than five times the thickness. Any plate up to 4 in. (101.60 mm), thick inclusive, is covered by this specification.

[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] The boldface numbers in parentheses refer to the list of references at the end of this standard.

[3] 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.

[4] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

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

[6] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

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

4.4 *Bar*—Rounds, flats, or other shapes from 0.1875 in. (4.76 mm) to 4 in. (101.60 mm) in diameter or thickness. (Other sizes and shapes by special order.)

4.5 *Wire*—Rounds, flats, or other shapes less than 3⁄16 in. (4.76 mm) in diameter or thickness.

5. Ordering Information

5.1 Include with inquiries and orders for material under this specification the following information.

5.1.1 Quantity,

5.1.2 Applicable ASTM designation and date of issue,

5.1.3 Form (strip, sheet, plate, bar, or wire),

5.1.4 Condition (see Section 3 and 6.1),

5.1.5 Mechanical properties (if applicable for special conditions),

5.1.6 Finish (see 6.2),

5.1.7 Applicable dimensions including size, thickness, width, length, or drawing number,

5.1.8 Special tests, if any, and

5.1.9 Special requirements.

6. Materials and Manufacture

6.1 *Finish*—The mill product may be furnished to the implant manufacturer as descaled or pickled, abrasive-blasted, chemically milled, ground, machined, peeled, polished, or as specified by the purchaser. On billets, bars, plates, and forgings, it is permissible to remove minor surface imperfections by grinding if the resultant area meets the dimensional and surface finish requirements of this section.

6.2 *Condition*—Material shall be furnished in the beta annealed condition.

7. Chemical Requirements

7.1 The heat analysis shall conform to the chemical composition of Table 1. Ingot analysis may be used for reporting all chemical requirements, except hydrogen. Samples for hydrogen shall be taken from the finished mill product, and the supplier shall not ship material with chemistry outside the requirements specified in Table 1.

7.1.1 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 verify compliance with this specification.

7.2 *Product Analysis*:

7.2.1 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. The manufacturer shall not ship material that is outside the limits specified in Table 1. The product analysis tolerances shall conform to the product tolerances in Table 2.

7.2.2 The product analysis is either for the purpose of verifying the composition of a heat or manufacturing lot or to determine variations in the composition within the heat.

7.2.3 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product analysis. Product analyses outside the tolerance limits allowed in Table 2 are cause for rejection of the product. A referee analysis may be used if agreed upon by the supplier and purchaser.

7.2.4 For referee purposes, use Test Methods, E 1409, E 1447, and E 2371 or other analytical methods agreed upon between the purchaser and the supplier.

7.3 Samples for chemical analysis are representative of the material being tested. The utmost care must be used in sampling titanium for chemical analysis because of its affinity for elements such as oxygen, nitrogen, and hydrogen. In cutting samples for analysis, therefore, the operation should be carried out insofar as possible in a dust-free atmosphere. Cutting tools should be clean and sharp. Samples for analysis should be stored in suitable containers.

8. Mechanical Requirements

8.1 The material supplied under this specification shall conform to the mechanical property requirements in Table 3 or Table 4.

8.2 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 the specified yield and then the crosshead speed shall be increased so as to produce fracture in approximately one additional minute.

8.3 For sheet and strip, the bend test specimen shall withstand being bent cold through an angle of 105° without fracture in the outside surface of the bend portion. The bend shall be made over a mandrel with a diameter equal to that shown in Table 4. Test conditions shall conform to Test Method E 290.

8.4 *Number of Tests*:

8.4.1 *Bar, Forging Bar, Shapes, and Wire*—Perform at least one tension test from each lot in the longitudinal direction. Should this test result 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.

8.4.2 Tensile test results for which any specimen fractures outside the gauge length shall be considered acceptable, if both

TABLE 1 Chemical Requirements

Element	Composition, %, (Mass/Mass)
Nitrogen, max	0.05
Carbon, max	0.10
Hydrogen, max	0.015
Iron, max	0.10
Oxygen, max	0.20
Molybdenum	14.00-16.00
Titanium[A]	balance

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

TABLE 2 Product Analysis Tolerances[A]

Element	Tolerance Under the Minimum or Over the Maximum Limit[B], %, (Mass/Mass)
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.0020
Iron	0.10
Oxygen	0.02
Molybdenum	0.25

[A] Refer to AMS 2249.

[B] Under the minimum limit not applicable for elements in which only a maximum percentage is indicated.