Designation: F2066 – 13ε1

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

This standard is issued under the fixed designation F2066; 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 wrought titanium-15 molybdenum alloy to be used in the manufacture of surgical implants (**1**).[2]

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 each other. Combining values from the two systems may result in non-conformance with the standard.

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E8/E8M Test Methods for Tension Testing of Metallic Materials

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

E112 Test Methods for Determining Average Grain Size

E290 Test Methods for Bend Testing of Material for Ductility

E539 Test Method for Analysis of Titanium Alloys by X-Ray Fluorescence Spectrometry

E1409 Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by Inert Gas Fusion

E1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by Inert Gas Fusion Thermal Conductivity/Infrared Detection Method

E1941 Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis

E2371 Test Method for Analysis of Titanium and Titanium Alloys by Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry (Performance-Based Test Methodology)

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

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

F1408 Practice for Subcutaneous Screening Test for Implant Materials

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

2.2 *Aerospace Material Specifications:*[4]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 2631 Ultrasonic Inspection — Titanium and Titanium Alloy Bar and Billet

AMS 2380 Approval and Control of Premium Quality Titanium Alloys

2.3 *ISO Standards:*[5]

ISO 6892 Metallic Materials — Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems Requirements

2.4 *American Society for Quality Standard:*

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

[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**

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

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

3.1.2 *alpha + beta annealed + aged, n*—the condition of the material that is obtained by reheating the alpha + beta annealed material to a time-temperature combination below the beta transus to increase the strength of the alloy.

3.1.3 *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].

3.1.4 *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 a width greater than five times the thickness. Any plate up to 4 in. [101.60 mm], thick inclusive, is covered by this specification.

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 *Forging Bar*—Bar as described in 4.4 used for production of forgings, may be furnished in the hot worked condition.

4.6 *Wire*—Rounds, flats, or other shapes less than 3⁄16 in. [4.76 mm] in diameter or thickness.

4.7 *Other*—Other forms and shapes, including tubing, may be provided by agreement between purchaser and supplier.

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, forging bar, wire, other),

5.1.4 Condition (see Section 3 and 6.2),

5.1.5 Mechanical properties (if applicable for special conditions),

5.1.6 Finish (see 6.1),

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, combinations of these operations, 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 specification.

6.2 *Condition:*

6.2.1 *Beta Annealed*—Material shall be furnished in the beta annealed condition. Two classes of beta annealed sheet, strip, and plate are available. If no class is chosen, Class 1 product shall be provided.

6.2.2 *Alpha + Beta Annealed*—Material shall be furnished in the alpha + beta annealed condition.

6.2.3 *Alpha + Beta Annealed + Aged*—Material shall be furnished in the alpha + beta annealed + aged 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.

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.

7.2.4 For referee purposes, use Test Methods, E539, E1409, E1447, E1941, and E2371 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 E8/E8M. 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 E290.

8.4 *Number of Tests:*

8.4.1 *Bar, Forging Bar, Shapes, and Wire*—Test according to Test Methods E8/E8M. Perform at least one tension test from each lot in the longitudinal direction. Should any test specimen not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test specimen. 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 the elongation and the reduction of area meet the minimum requirements specified. Refer to sections 7.11.4 and 7.12.5 of Test Methods E8/E8M. If either the elongation or 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.

8.4.3 *Sheet, Strip, and Plate*—Test according to Test Methods E8/E8M. Perform at least one tension test from each lot in the longitudinal direction. Perform at least one bend test from each lot in both the longitudinal and transverse directions. Tests in the transverse direction need be made only on product from which a specimen not less than 8.0 in. (200 mm) in length for sheet, and 2.50 in. (64 mm) 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 specimen. The lot shall be considered in compliance only if all additional test pieces meet the specified requirements.

9. Dimensions, Mass, and Permissible Variations

9.1 *Units of Measure:*

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

9.1.1.1 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.

9.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's PO, specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification.

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

9.1.2 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units

TABLE 3 Mechanical Properties—Bar and Wire

Condition[A]	Ultimate Tensile Strength, min, psi [MPa]	Yield Strength (0.2 % Offset), min, psi [MPa]	Elongation[B] in 2 in. [50 mm] 4D or 4W, min, %	Reduction of Area, min, %
Beta Annealed	100 000 [690]	70 000 [483]	20	60
Alpha + Beta Annealed[C,D]	130 500 [900]	116 000 [800]	10	25
Alpha + Beta Annealed + Aged	166 750 [1150]	152 250 [1050]	10	25

[A] Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and purchaser.
[B] Elongation of material 0.063 in. [1.6 mm] or greater in diameter (D) or width (W) shall be measured using a gauge length of 2 in. or 4D or 4W. The gauge 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. Alternatively, a gauge length corresponding to ISO 6892 may be used when agreed upon between the supplier and purchaser. (5.65 times the square root of So, where So is the original cross sectional area.) The gauge length shall be reported with the elongation value.
[C] Mechanical properties for the hot rolled condition may be established by agreement between the supplier and purchaser.
[D] Up to 4.00-in. [101.60-mm] diameter or thickness.

TABLE 4 Mechanical Properties—Sheet, Strip, and Plate[A]

Condition[A]	Ultimate Tensile Strength, min, psi [MPa]	Yield Strength (0.2 % Offset), min, psi [MPa]	Elongation[C] in 2 in. [50 mm], min, %	Bend Test Mandrel Diameter[B]	
				Under 0.070 in. [1.78 mm] in Thickness	0.070 to 0.1875 in. [1.78 to 4.76 mm] in Thickness
Beta Annealed, Class 1	105 000 [724]	80 000 [552]	12	5T	6T
Beta Annealed, Class 2	100 000 [690]	70 000 [483]	20	5T	6T

[A] Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and purchaser.
[B] T equals the thickness of the bend test specimen. Bend tests are not applicable to material over 0.1875 in. [4.76 mm] in thickness. The limits listed apply to tests taken both longitudinally and transversely to the direction of rolling.
[C] Elongation of material 0.063 in. [1.6 mm] or greater in diameter (D) or width (W) shall be measured using a gauge length of 2 in. or 4D or 4W. The gauge 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. Alternatively, a gauge length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser. (5.65 times the square root of So, where So is the original cross sectional area.) The gauge length shall be reported with the elongation value.

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 of that standard provides conversion tables and Annex B provides rules for conversion and significance.

10. Special Requirements

10.1 *Microstructure:*

10.1.1 *Beta Annealed*—The microstructure shall consist of a fully recrystallized beta phase structure. Primary alpha and alpha prime (also known as martensitic alpha) are not permitted in the microstructure when viewed at 100× magnification. The grain size in the annealed condition shall be 5 or finer, in accordance with Test Methods E112.

10.1.2 *Alpha + Beta*—The microstructure shall be a fine dispersion of the alpha and beta phases resulting from processing in the alpha plus beta field. There shall be no continuous alpha network at prior beta grain boundaries. There shall be no coarse, elongated alpha platelets.

10.2 Determine the beta transus temperature for each heat by a suitable method and report on the material certification if required by the purchaser.

10.3 Alpha case is not permitted for products supplied with a machined, ground, or chemically milled surface finish. For other products, there will be no continuous layer of alpha case >0.001 in. [0.025 mm] when examined at 100× magnification.

11. Ultrasonic Inspection

11.1 All centerless ground or peeled and polished round bar >0.375 in. [9.5 mm] in nominal diameter shall be ultrasonically inspected at final diameter according to AMS 2631, Class A1. Equivalent test methods may be substituted when agreed upon by the purchaser and supplier.

NOTE 1—AMS 2631 contains varying flat bottom hole (FBH) requirements based on melting grades per AMS 2380. Since the FBH requirement for Class 1 is the same, regardless of the melting grade, it is not necessary to specify the melting grade.

12. Significance of Numerical Limits

12.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or 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.

13. Certification

13.1 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.

14. Quality Program Requirements

14.1 The supplier shall maintain a quality program such as defined in ASQ C1, ISO 9001, or similar quality program.

15. Keywords

15.1 metals (for surgical implants); orthopaedic medical devices; titanium alloys; titanium alloys (for surgical implants)

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the chemical, mechanical, and metallurgical properties of wrought titanium-15 molybdenum alloy to be used in the manufacture of surgical implants (**1-4**).

X1.2 The microstructural requirements contained in this specification represent current general consensus with respect to optimization of mechanical properties for implant applications.

X1.3 The minimum mechanical properties specified ensure a baseline of strength and ductility for the highly stressed devices for which this alloy is typically used.

X1.4 The stress corrosion cracking resistance of this alloy is similar to that of titanium-6 aluminum-4 vanadium ELI alloy (**5**).

X1.5 ISO standards are listed for reference only. Use of the ISO standard instead of the preferred ASTM standards may be agreed upon between the purchaser and supplier.

X1.6 The various titanium mill products covered in this specification normally are formed with the conventional forging and rolling equipment found in primary ferrous and nonferrous plants. The material is usually multiple melted in arc furnaces (including furnaces such as plasma arc and electron beam) of a type conventionally used for reactive metals.

X2. BIOCOMPATIBILITY

X2.1 The suitability of this material from a human implant perspective depends on the specific application. The biological tests appropriate for the specific site, such as recommended in Practice F748, should be used as a guideline. A summary of the *in-vitro* and animal testing that has been performed as of the approval date of this specification is provided in X2.3. This alloy is covered by 510k filing #'s K952272, K962616, K963798, K974555, and K982732.

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. The alloy composition covered by this specification, however, has been subjected to testing in laboratory animals, and has been used clinically since Feb. 6, 1998. The results of these studies indicate a well-characterized level of local biological response that is equal to or less than that produced by the reference material unalloyed titanium (see Specification F67) that has a long history of successful clinical application in soft tissue and bone implants in humans.

X2.3 As of the time of the original approval of this specification, this titanium alloy material had a limited history of clinical use in humans. An extensive series of *in-vitro* and animal studies had been performed as follows, comparing the biological response to that of a reference material. These tests were conducted to support the usage of this material in surgical implant devices (**6-10**). In all cases, the results indicated that this material was no more reactive with the environment than the reference material.

X2.3.1 L929 MEM-Cytotoxicity (**11**).

X2.3.2 Molybdenum Sensitization Study (**12**).

X2.3.3 Molybdenum *In-Vitro* Organ Culture (**13**).

X2.3.4 Rabbit Pyrogen Test (**6**).

X2.3.5 Acute Systemic Toxicity (Albino Swiss mice) (**6**).

X2.3.6 Practice F1408 Subcutaneous Implantation in Mice (**1**).

X2.3.7 Practice F981 Implantation in Dogs (**1**).

X2.3.8 Ames Mutagenicity Assay (**14**).

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(2) Disegi, J. and Fairer, R., "Torsional Properties of Ti-15Mo Bone Screws," *Transactions*, 21st Annual Meeting, Society for Biomaterials, 18-22 March 1995, p. 351.

(3) Meusli, P., et al., "Properties of Surface Oxides on Titanium and Some Titanium Alloys," *Proceedings*, Sixth World Conference on Titanium, 6-9 June 1988, pp. 1759-1764.

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(7) FDA 510(k) No. K962616.

(8) FDA 510(k) No. K963798.

(9) FDA 510(k) No. K974555.

(10) FDA 510(k) No. K982732.

(11) Disegi, J. and Paika, I., "Cytotoxicity Evaluation of Ti-15Mo Alloy," *Transactions*, 20th Annual Meeting, Society for Biomaterials, 1994, p. 202.

(12) Hierholzer, S., and Hierholzer, G., *Internal Fixation and Metal Allergie: Clinical Investigations, Immunology, and Histology of the Implant Tissue Interface*, Thieme Medical Publishers, New York, 1992.

(13) Gerber, H., and Perren, S., "Evaluation of Tissue Compatibility of in vitro Cultures of Embryonic Bone," *Evaluation of Biomaterials*, John Wiley & Sons, 1980, pp. 307-314.

(14) Disegi, J., and Prezioso, J., "Mutagenicity Evaluation of Ti-15Mo Alloy," *Transactions*, 5th World Biomaterials Congress, 29 May–2 June 1996, p. 675.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F2066 – 11) that may impact the use of this standard. (Approved October 1, 2013.)

(1) Alpha + beta annealed + aged condition was added to Section 3 and 6.2. Mechanical properties for the alpha + beta annealed + aged condition were added to Table 3.

(2) Ultrasonic inspection requirements were added as Section 11.

(3) Scope 1.2 units of measure, Reference Documents, Dimensional and Permissible Variations, and other editorial corrections were made to meet terminology and formatting 20guidelines established for implant material standards within F04.12.