Designation: F 2066 – 01

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:*

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

E 112 Test Methods for Determining Average Grain Size[3]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[4]

E 290 Test Methods for Bend Testing of Material for Ductility[3]

E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique[5]

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method[5]

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications[6]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[6]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[6]

F 1408 Practice for Subcutaneous Screening Test for Implant Materials[6]

2.2 *Aerospace Material Specification:*

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys[7]

2.3 *American Society for Quality Standard:*

ASQ C1 Specification of General Requirements for a Quality Program[8]

2.4 *ISO Standard:*

ISO 6892 Metallic Materials — Tensile Testing[9]

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. Plate up to 4 in. (101.60 mm), thick inclusive, is covered by this specification.

4.4 *Bar*—Rounds or flats 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 or flats less than 0.1875 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,

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[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.

Current edition approved May 10, 2001. Published May 2001. Orinially published as F 2066 - 00. Last previous edition F 2066 - 00.

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

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

[4] *Annual Book of ASTM Standards*, Vol 03.05.

[5] *Annual Book of ASTM Standards*, Vol 03.06.

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

[7] Available from the American Society of Automotive Engineers, 400 Commonwealth Dr., Warrendale, PA 15096.

[8] Available from the American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

[9] Available from the American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

5.1.2 Applicable ASTM designation,
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 dimension including size, thickness, width, or drawing number,
5.1.8 Special tests, if any, and
5.1.9 Special requirements.

6. Materials and Manufacture

6.1 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 alloy is usually multiple melted in arc furnaces (including furnaces such as plasma arc and electron beam) of a type conventionally used for reactive metals.

6.2 *Finish*—The mill product may be furnished to the implant manufacturer as descaled or pickled, sandblasted, chemically milled, ground, machined, peeled, polished, or combinations of these operations.

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.

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*—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 check tolerances in Table 2.

7.2.1 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.

7.2.2 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this check analysis.

7.3 For referee purposes, use Test Methods E 120, E 1409, and E 1447 or other analytical methods agreed upon between the purchaser and the supplier.

7.4 Ensure that the 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.

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.

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 *Number of Tests*—Perform a minimum of two tension tests from each lot. A lot is defined as the total number of mill products produced under the same conditions at essentially the same time. If either of the two test specimens does not meet the specified requirements, test two additional test pieces representative of the same lot in the same manner. The lot will be considered in compliance only if both additional test pieces meet the specified requirements. If a specimen fails outside the gage, the test is null in accordance with Test Methods E 8, and a retest shall be performed.

8.4 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.

9. Special Requirements

9.1 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.

9.2 The grain size in the annealed condition shall be 5 or finer, in accordance with Test Methods E 112.

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

9.4 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 when examined at 100× magnification.

TABLE 3 Mechanical Properties—Bar and Wire

Condition	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength (0.2 % Offset), min, psi (MPa)	Elongation[A] in 4D or 4W, min, %	Reduction of Area, min, %
Beta annealed	100 000 (690)	70 000 (483)	20	60

[A]4D = 4X diameter; 4W = 4X width. Alternately, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser.

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

Condition	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength (0.2 % Offset), min, psi (MPa)	Elongation 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	105 000 (724)	80 000 (552)	12	5T	6T

[A]Limits apply to tests taken both longitudinal and transverse to the direction of rolling.
[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.

10. Certification

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

11. Quality Program Requirements

11.1 The producer shall maintain a quality program in accordance with ASQ C1.

12. Keywords

12.1 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)**.

X2. BIOCOMPATIBILITY

X2.1 The suitability of this material from a human implant perspective is dependent on the specific application. The biological tests appropriate for the specific site, such as recommended in Practice F 748 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.

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 F 67) 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 F 1408 Subcutaneous Implantation in Mice **(1)**.
X2.3.7 Practice F 981 Implantation in Dogs **(1)**.
X2.3.8 Ames Mutagenicity Assay **(14)**.

REFERENCES

(**1**) Zardiackas, L., Mitchell, D., and Disegi, J., "Characterization of Ti-15Mo Beta Titanium Alloy for Orthopaedic Implant Applications," *Medical Applications of Titanium and Its Alloys: The Material and Biological Issues, ASTM STP 1272*, S. Brown and J. Lemons, Eds., American Soceity for Testing and Materials, W. Conshohocken, PA, 1996, pp. 60-75.
(**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.
(**4**) Khan, M.A., Williams, R.L., and Williams, D.F., "In-Vitro Corrosion and Wear of Titanium Alloys in the Biological Environment," *Biomaterials*, Vol 17, No 22, 1996, pp. 2117-2126.
(**5**) Bogan, J., Zardiackas, L., Disegi, J., "Stress Corrosion Cracking Resistance of Titanium Implant Materials," *Transactions*, 27th Annual Meeting, Society for Biomaterials, 24–29 April 2001, p. 438.
(**6**) FDA 510(k) No. K952272.
(**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 F 2066 - 00 that may impact the use of this standard.

(*1*) Test Methods E 290 was added to the Referenced Documents section.
(*2*) 8.4 was added to cover the bend test requirement.
(*3*) Table 4, Footnote B was clarified.
(*4*) Reference **(5)** citation was changed from an internal report to a peer-reviewed publication in the 2001 edition of this standard.