Designation: F 1813 – 01

Standard Specification for Wrought Titanium – 12 Molybdenum – 6 Zirconium – 2 Iron Alloy for Surgical Implant (UNS R58120)[1]

This standard is issued under the fixed designation F 1813; 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 – 12 molybdenum – 6 zirconium – 2 iron alloy to be used in the manufacture of surgical implants.[2]

1.2 The values stated in inch-pound units are to be regarded as the standard. The SI equivalents given in parentheses are provided 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 1409 Test Method for the Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique[5]

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

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 Materials Specification:*

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

TABLE 1 Chemical Requirements

Element	Composition %, Mass/Mass	
	Min	Max
Molybdenum	10.0	13.0
Zirconium	5.0	7.0
Iron	1.5	2.5
Oxygen	0.008	0.28
Nitrogen	—	0.05
Carbon	—	0.05
Hydrogen	—	0.020
Titanium[A]	balance	balance

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

2.3 *ISO Standards:*

ISO 6982 Metallic Materials Tensile Testing at Ambient Temperature[8]

2.4 *American Society for Quality Standard:*

ASQ C1 Specification of General Requirements for a Quality Program[9]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

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

4. Product Classification

4.1 *Bar*—Rounds or flats from 3⁄16 in. (4.76 mm) to 4 in. (101.60 mm) in diameter or thickness (other sizes and shapes by special order).

4.2 *Wire*—Rounds or flats 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 shall include the following information:

5.1.1 Quantity,

5.1.2 ASTM designation and date of issue,

5.1.3 Form (bar or wire),

[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 F0.4.12 on Metallurgical Materials.

Current edition approved Oct. 10, 2001. Published February 2002.

[2] FDA 510K application number K903630.

[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 15096-0001.

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

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

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

5.1.4 Condition (see 6.3),

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,

5.1.9 Other 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.

6.3 *Condition*—Material shall be furnished in the annealed or as rolled 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. 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*—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.

TABLE 2 Product Analysis Tolerances[A]

Element	Tolerance Under the Minimum or Over the Maximum Limit[B]
Molybdenum	0.25
Zirconium over 4 to 6 % inclusive	0.20
Zirconium over 6 to 10 % inclusive	0.30
Iron	0.20
Oxygen up to 0.2 %	0.02
Oxygen over 0.2 %	0.03
Nitrogen	0.02
Carbon	0.002
Hydrogen	0.0002

[A] Refer to AMS 2249.

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

7.2.1 The product analysis is either for the purpose of verifying the composition of a heat or 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 product analysis.

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

8. Mechanical Requirements

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

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 yield and then the crosshead speed may be increased so as to produce fracture in approximately 1 min.

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. Should either of the two test specimens 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.

9. Special Requirements

9.1 The microstructure shall be fully recrystallized single-phase beta microstructure after solution annealing. The grain size in the annealed condition shall be 5 or finer based upon Test Methods E 112.

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

9.3 Alpha case is not permitted for products supplied with a machined, ground, or chemically milled surface finish. For

TABLE 3 Solution-Annealed Mechanical Properties

Size, in. (mm)	Tensile Strength, min, psi (MPa)	Yield Strength (0.2 % Offset), min, psi (MPa)	Elongation[A] in 2 in. or 4*D* or 4*W* min, %	Reduction of Area, min (%)
All	135 000 (931.5)	130 000 (897)	12	30

[A] Elongation of material 0.062 in. (1.575 mm) or greater in diameter (*D*) or width (*W*) shall be measured using a gage length of 2 in. or 4*D* or 4*W*. The gage length must be reported with the test results. The method for determining elongation of material under 0.062 in. (1.575 mm) in diameter or thickness may be negotiated. Alternately, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser (5.65 $\sqrt{So}$, where *So* is the original cross-sectional area).