Designation: F1813 – 06

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

This standard is issued under the fixed designation F1813; 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 for surgical implants 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 in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E8 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

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

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

E2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry

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

2.2 *Aerospace Materials Specification:*

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

2.3 *ISO Standards:*

ISO 6982 Metallic Materials Tensile Testing at Ambient Temperature[5]

ISO 9001 Quality Management Standard[5]

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

3.1.2 *lot, n*—the total number of mill products produced from the same melt heat under the same conditions at essentially the same time.

4. Product Classification

4.1 *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.)

4.2 *Forging Bar*—Bar as described in 4.1 used in the production of forgings. This product may be furnished in the as rolled condition.

4.3 *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 ASTM designation and date of issue,

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

5.1.4 Condition (see 6.3),

5.1.5 Mechanical properties (if applicable for special conditions),

5.1.6 Finish (see 6.2),

[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 Dec. 1, 2006. Published January 2007. Originally approved in 1997. Last previous edition approved in 2001 as F1813 – 01. DOI: 10.1520/F1813-06.

[2] FDA 510K application number K903630.

[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

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

5.1.8 Special tests, if any, and

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 non ferrous plants. This alloy is usually multiple melted in arc furnaces (including plasma arc and electron beam) of a type conventionally used for reactive metals.

6.2 *Finish*—The mill product may be supplied as specified by the purchaser with a descaled or pickled, abrasive blasted, chemically milled, ground, machined, peeled, or polished finish. 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.

6.3 *Condition*—Material shall be furnished in the solution annealed or warm worked (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:*

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 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.

TABLE 1 Chemical Requirements

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

[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]
Nitrogen	0.02
Carbon	0.002
Hydrogen	0.0002
Iron	0.20
Molybdenum	0.25
Zirconium over 4 to 6 %, inclusive	0.20
Zirconium over 4 to 6 %, inclusive	0.30
Oxygen up to 0.2 %	0.02
Oxygen over to 0.2 %	0.03

[A] Refer to AMS 2249.
[B] Under the minimum limit not applicable for elements where only a maximum percentage is indicated.

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 analyses. Product analysis 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 supplier and purchaser.

7.2.4 For referee purposes, use Test Methods E2371, E1409, and E1447 or other analytical methods agreed upon between the purchaser and the supplier.

7.3 Samples for chemical analysis shall be 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. Alternative properties may be agreed upon between the purchaser and supplier.

8.2 Specimens for tension tests shall be machined and tested in accordance with Test Methods E8. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in./min

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), 4*D* or 4*W* min %	Reduction of Area min, %
Solution annealed	135 000 (931.5)	130 000 (897)	12	30

[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 4*D* or 4*W*. 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. Alternately, 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).