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]

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),

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

[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.

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[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.

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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.

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.

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.

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.

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).

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 other products, there will be no continuous layer of alpha case when examined at 100× magnification.

10. Certification

10.1 The supplier shall provide a certification that the material was tested in accordance with this specification. A report of the test results shall be furnished to the purchaser at the time of shipment.

11. Quality Program Requirements

11.1 The producer shall maintain a quality program as defined in 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, physical, mechanical, and metallurgical properties of wrought titanium-12 molybdenum-6 zirconium-2 iron alloy to be used in the manufacture of surgical implants.[2]

X1.2 The microstructural requirements contained in this specification represent the 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.[2]

X1.5 ISO standards are listed for reference only. Use of an ISO standard, in addition to or instead of a preferred ASTM standard, may be negotiated between the purchaser and supplier.

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. In all cases, the results indicated that this material was no more reactive with the environment than the reference material.

X2.3.1 Acute systemic toxicity by mouse injection,[2]

X2.3.2 Cytotoxicity by agar overlay,[2]

X2.3.3 Hemolytic potential by direct exposure,[2]

X2.3.4 Dermal sensitization by guinea pig maximization,[2]

X2.3.5 Mutagenicity by the Ames test (saline and DMSO extracts),

X2.3.6 Response to particulate debris (release of IL-1, IL-6 and PGE_2 in cell culture and ex-vivo histology rabbits).[2]

SUMMARY OF CHANGES

(*1*) Added 6.3 which allows for material to be supplied in the as rolled condition.

(*2*) Editorial corrections have been made to meet terminology and formatting guidelines established for implant material standards.

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