



Designation: F 1813 – 97^{ε1}

Standard Specification for Wrought Titanium - 12 Molybdenum - 6 Zirconium - 2 Iron Alloy For Surgical Implant Applications¹

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.

^{ε1} NOTE—Footnote 1 was editorially revised June 2000.

1. Scope

1.1 This specification covers the chemical, mechanical and metallurgical requirements for wrought Ti-12 Mo-6 Zr-2 Fe alloy to be used in the manufacture of surgical implants².

1.2 The values stated in inch-pound units are to be regarded as the standard. The metric equivalents given in parentheses are provided for information only.

2. Referenced Documents

2.1 ASTM Standards:

B 348 Specification for Titanium and Titanium Alloy Bars and Billets³

E 8 Test Methods for Tension Testing of Metallic Materials⁴

E 112 Test Methods for Determining Average Grain Size⁵

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys⁴

E 1409 Test Method for the Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique⁴

E 1447 Test Method for the Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method⁴

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices⁶

F 750 Practice for Evaluating Material Extracts by Systematic Injection in the Mouse⁶

F 895 Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity⁶

F 981 Practice for Assessment of Compatibility of Biomaterials (Non-Porous) for Surgical Implants with Respect to Effect of Materials on Muscle and Bone⁶

¹ This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F0.4.12 on Metallurgical Materials.

Current edition approved June 10, 1997. Published June 1998.

² Wang, K., Gustavson, L., Dumbleton, J., "The Characterization of Ti-12Mo-6Zr-2Fe - A New Biocompatible Alloy Developed for Surgical Implants", *Beta Titanium Alloys in the 1990's*, Proceedings of a Symposium on Beta Titanium Alloys held at the 1993 Annual TMS meeting in Denver, Colorado, February 22–24, 1993.

³ *Annual Book of ASTM Standards*, Vol 02.04.

⁴ *Annual Book of ASTM Standards*, Vol 03.01.

⁵ *Annual Book of ASTM Standards*, Vol 03.05.

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

2.2 Aerospace Materials Specification:

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys⁷

2.3 American Society for Quality Standard:

ASQ C1 Specification of General Requirements for a Quality Program⁸

3. Ordering Information

3.1 Inquiries and orders for material under this specification shall include the following information:

3.1.1 Quantity (weight or number of pieces),

3.1.2 ASTM Designation,

3.1.3 Dimensions,

3.1.4 Condition,

3.1.5 Finish (see 4.2), and

3.1.6 Special requirements.

4. Materials and Manufacture

4.1 The titanium mill products covered in this specification are normally formed with the conventional forging, rolling or other metal processing equipment found in primary ferrous and nonferrous plants. The ingot metal for such mill operations is usually multiple melted in arc furnaces (including furnaces such as plasma arc and electron beam) of a type conventionally used for reactive metals.

4.2 *Finish*—Annealed material may be furnished to the implant manufacturer as descaled or pickled, sandblasted, machined, ground, or combinations of these operations.

5. Chemical Requirements

5.1 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.

5.2 *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. Product analysis limits

⁷ Available from SAE; 400 Commonwealth Drive, Warrendale, PA 15096.

⁸ Available from American Society for Quality; 161 West Wisconsin Avenue, Milwaukee, WI 53203.

TABLE 1 Chemical Requirements

Element	Composition, Weight %	
	Minimum	Maximum
Molybdenum	10.0	13.0
Zirconium	5.0	7.0
Iron	1.5	2.5
Oxygen	0.08	0.28
Nitrogen	—	0.05
Carbon	—	0.05
Hydrogen	—	0.020
Titanium ^A	Balance	Balance

^AThe percentage of titanium is determined by difference and need not be determined or certified.

shall be as specified in Table 2.

5.2.1 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.

5.3 For referee purposes, Test Methods E 120, E 1409 and E 1447 or other analytical methods agreed upon by purchaser and supplier shall be used.

5.4 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. Therefore, in cutting samples for analysis any contamination should be avoided. Chips should be clean, and sharp cutting tools should be used. Samples for analysis should be stored in suitable containers.

5.5 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.

6. Mechanical Requirements

6.1 Material supplied under this specification shall conform to the mechanical property requirements given in Table 3.

6.2 Perform tension testing in accordance with Test Methods E 8. Determine tensile properties using a strain rate of

TABLE 3 Mechanical Properties of Ti-12Mo-6Zr-2Fe Bar and Wire^A

Condition	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength (0.2 %), min, psi (MPa)	Elongation ^B , min, %	Reduction in Area min. (%)
Solution ^C Annealed	135 000 (931.5)	130 000 (897)	12	30

^ADiameter 0.10 in. (2.54 mm) to 1½ in. (38.1 mm).

^BGage length = 4 × diameter.

^CSolution annealing shall be performed at 1450 ± 25°F (788 ± 14°C) followed by a rapid quench to below 300°F (°C), for an appropriate time, as required to meet grain size and mechanical property requirements.

0.003 to 0.007 in./in./min (mm/mm/min) through the specified yield strength, and then the cross-head speed shall be increased so as to produce fracture in approximately one additional minute.

6.3 *Number of Tests*—A minimum of two tension tests shall be made 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 test specimens not meet the specific requirements two additional test pieces representative of the same lot shall be tested in the same manner. The lot shall be deemed to comply only if both additional test pieces meet the specific requirements. If a sample fails outside the gage section, the sample is void in accordance with Test Method E 8 and additional sample shall be tested.

7. Microstructure

7.1 The microstructure shall be fully recrystallized single phase beta microstructure after solution annealing. There shall be no continuous alpha network at prior beta grain boundaries. There shall be no alpha precipitates.

7.2 Grain size of the solution annealed barstock shall be five or finer based upon Test Methods E 112.

7.3 Products supplied with a machined or ground surface finish shall have no alpha case. For other products, there shall be no continuous layer of alpha case when examined at 100X.

7.4 The beta transus temperature shall be determined by a suitable method and reported on the material certification for each heat.

8. Quality Program Requirements

8.1 The producer shall maintain a quality program, for example, such as defined in ASQ C1.

9. Certification

9.1 A certification shall be provided by the manufacturer of the material that the material was manufactured and tested in accordance with this specification. A report of the test results shall be furnished at the time of shipment.

10. Keywords

10.1 metals (for surgical implants); orthopaedic medical devices; titanium alloys; titanium/titanium alloy; titanium/titanium alloys (for surgical implants)

TABLE 2 Permissible Variation in Product Analysis (Weight %)

Element	Tolerance Under Minimum or Over Maximum Limit
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