



Designation: F 1813 – 97^{ε1}

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

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^{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.

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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.