



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 Materials³

E 112 Test Methods for Determining Average Grain Size³

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 Technique⁵

E 1447 Test Method for the Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method⁵

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

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone⁶

F 1408 Practice for Subcutaneous Screening Test for Implant Materials⁶

2.2 Aerospace Materials Specification:

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys⁷

2.3 ISO Standards:

ISO 6982 Metallic Materials Tensile Testing at Ambient Temperature⁸

2.4 American Society for Quality Standard:

ASQ C1 Specification of General Requirements for a Quality Program⁹

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 $\frac{3}{16}$ 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 $\frac{3}{16}$ 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 F04.12 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.