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Standard Specification for Wrought Titanium-12Molybdenum-6Zirconium-2Iron 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-12molybdenum-6zirconium-2iron alloy mill products to be used in the manufacture of surgical implants.[2]

1.2 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems shall not be combined.

1.3 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E8/E8M 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 Inert Gas Fusion

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

E1941 Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis

E2371 Test Method for Analysis of Titanium and Titanium Alloys by Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry (Performance-Based Test Methodology)

E2626 Guide for Spectrometric Analysis of Reactive and Refractory Metals (Withdrawn 2017)[4]

~~F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)~~

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

IEEE/ASTM SI 10 American National Standard for Metric Practice

[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.

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[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] The last approved version of this historical standard is referenced on www.astm.org.

***A Summary of Changes section appears at the end of this standard**

2.2 *Aerospace Materials ~~Specification:~~Specifications:*[5]
AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys
AMS 2631 Ultrasonic Inspection—Titanium and Titanium Alloy Bar, Billet and Plate
AMS 2380 Approval and Control of Premium-Quality Titanium Alloys
2.3 *ISO Standards:*[6]
ISO 6982 Metallic Materials Tensile Testing at Ambient Temperature
ISO 9001 Quality Management Standard

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 *hot work, n*—any mechanical deformation process performed above the recrystallization temperature.

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

3.1.4 *solution anneal, v*—to heat treat in order to remove precipitates.

4. Product Classification

4.1 *Bar*—Rounds, flats, or other shapes from 0.188 in. ~~[4.76 mm]~~ [4.76 mm] to 4.0 in. [102 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 hot worked condition.

4.3 *Wire*—Rounds, flats, or other shapes less than 0.188 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 6.2),

5.1.5 Mechanical properties (if applicable for special conditions),

5.1.6 Finish (see 6.1),

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

5.1.8 Special ~~tests,~~tests (if any), and

5.1.9 Other requirements.

6. Materials and Manufacture

6.1 *Finish*—The mill product may be supplied as specified by the purchaser with a descaled or pickled, abrasive blasted,

[5] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.
[6] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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.

6.2 *Condition*—Material shall be furnished in the solution annealed or hot worked 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. The 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:~~ (Check) Analysis*—The product analysis tolerances shall conform to the product tolerances in Table 2 per AMS 2249. Product analysis tolerances do not broaden the specified heat (ladle or ingot) analysis requirements, but cover variations between laboratories in the measurement of chemical content.

7.2.1 Product (check) analysis ~~tolerances do not broaden the specified heat analysis requirements but cover variations in the measurement of chemical content between laboratories. The product analysis tolerances shall conform to the product tolerances~~limits are not for producer's use at producer's acceptance testing. Product analysis limits are not permitted to be applied to ladle or ingot analysis. The supplier shall not ship material that is outside the limits specified in Table ~~2~~1.

7.2.2 ~~The~~A product ~~analysis is~~ (check) analysis is one performed by the purchaser or supplier of the metal after it has been worked into semi-finished or finished forms or fabricated into parts, and is either for the purpose of verifying the composition of a heat or lot or to determine variations in the composition within the heat. In the analysis of finished parts, these values do not apply to elements whose percentage can be varied by fabrication techniques employed (for example, oxygen, nitrogen, hydrogen) unless the sample is sufficiently large to produce a reliable result, either for the purpose of verifying the composition of a heat or manufacturing lot or to determine variations in the composition within the heat.

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 analysis. 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 the supplier and purchaser.

7.2.4 For referee purposes, use Test Methods E2371, E1409, E1941, E2626, and E1447 or other analytical methods agreed upon between the purchaser and the supplier.

7.3 Samples for ~~chemical~~product 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~~ ability to react with elements such as oxygen, nitrogen, and hydrogen. ~~In~~ Therefore, when 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.

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.

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 prepared and tested in accordance with Test Methods E8/E8M. 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 one additional minute.

8.2.1 *Bar, Forging Bar, and Wire*—Test according to Test Methods E8/E8M. Perform at least one tension test from each lot in the longitudinal direction.

8.2.2 Tensile ~~tests~~test results for which any specimen fractures outside the gauge length shall be considered valid, if both the elongation and reduction of area meet the minimum requirements specified. If either the elongation or reduction of area is less than the minimum requirement, invalidate the specimen and retest. Retest one specimen for each invalidated specimen.

8.2.3 Should any test specimen not meet the specified requirements (except as noted in 8.2.2), test two additional test pieces representative of the same lot, in the same manner, for each failed test specimen. The lot will be considered in compliance only if all additional test pieces meet the specified requirements.

9. Dimensions and Permissible Variation

9.1 *Units of Measure:*

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 shall 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).

9.1.1 *Selection*—This specification requires that the purchaser selects the units (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

9.1.1.1 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

9.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's PO, specification, and engineering drawing are consistent, these units shall be used by the supplier for the product certification.

9.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.

9.1.2 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A provides conversion tables and Annex B provides rules for conversion and significant digits.

10. Special Requirements

10.1 The microstructure shall consist of a fully recrystallized beta phase structure. Primary alpha and alpha prime (also known as martensitic alpha) are not permitted in the microstructure when viewed at 100× magnification. The grain size in the annealed condition shall be 5 or finer based upon Test Methods E112.

10.2 Determine the beta transus temperature for each heat by a suitable method and report on the material certification if required by the purchaser.

10.3 Alpha case is not permitted for products supplied with a machined, ground, or chemically milled surface finish. For other products, there shall be no continuous layer of alpha case when examined at 100× magnification.

10.4 All centerless ground or peeled and polished round bar ≥0.375 in. [9.5 mm] in nominal diameter shall be ultrasonically inspected at final diameter according to AMS 2631 Class A1. Equivalent test methods may be substituted when agreed upon by the purchaser and supplier.

NOTE 1—AMS 2631 contains varying flat bottom hole (FBH) requirements based on melting grades per AMS 2380. Since the FBH requirement for Class A1 is the same regardless of the melting grade, it is not necessary to specify the melting grade.

11. Significance of Numerical Limits

11.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last ~~right hand~~ right-hand digit used in expressing the specification limit, in accordance with the rounding method of Practice E29.

12. Certification

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

12.2 Gauge length shall be reported with elongation.

13. Quality Program Requirements

13.1 The supplier shall maintain a quality program such as defined in ISO 9001 or similar quality program.

14. Keywords

14.1 metals (for surgical implants); orthopaedic medical devices; titanium alloys; titanium alloys (for surgical implants)