Designation: F3046 – 13

Standard Specification for Wrought Titanium-3Aluminum-2.5Vanadium Alloy for Surgical Implant Applications (UNS R56320)[1]

This standard is issued under the fixed designation F3046; 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-3aluminum-2.5vanadium alloy (R56320) to be used in the manufacture of surgical implants.

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 may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values of the two systems may result in nonconformance within the standard.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E8/E8M Test Methods for Tension Testing of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E290 Test Methods for Bend Testing of Material for Ductility

E539 Test Method for Analysis of Titanium Alloys by X-Ray Fluorescence Spectrometry

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)

2.2 *ISO Standards:*[3]

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems Requirements

2.3 *ASQ Standard:*[4]

ASQ C1 Specifications of General Requirements for a Quality Control Program

2.4 *Aerospace Material Specifications:*[5]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 2631 Ultrasonic Inspection—Titanium and Titanium Alloy Bar and Billet

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

4. Product Classification

4.1 *Strip*—Any product under 4.75 mm (0.1875 in.) in thickness and under 610 mm (24 in.) wide.

4.2 *Sheet*—Any product under 4.75 mm (0.1875 in.) in thickness and 610 mm (24 in.) or more in width.

4.3 *Plate*—Any product 4.75 mm (0.1875 in.) thick and over and 250 mm (10 in.) wide and over, with widths greater than five times thickness. Plate up to 101.60 mm (4.00 in.), thick inclusive is covered by this specification.

4.4 *Bar*—Round bars and flats from 4.75 mm (0.1875 in.) to 101.60 mm (4.00 in.) in diameter or thickness (other sizes and shapes by special order).

[1] This test method 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 Dec. 1, 2013. Published January 2014. DOI: 10.1520/F3046-13.

[2] 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.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

[5] Available from SAE International (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

Copyright © ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959. United States

TABLE 1 Annealed Mechanical Properties of Sheet, Strip, Plate, Bar, Wire, and Forgings

Nominal Diameter or Distance Between Parallel Sides, mm (in.)	Tensile Strength min, MPa (psi)	Yield Strength (0.2 % offset) min, MPa (psi)	Elongation[A] in 50 mm (2 in.), min, %	Reduction of Area[B] min, %
Under 4.75 (0.1875) thickness or diameter	620 (90 000)	485 (70 000)	15	...
4.75 (0.1875) to 101.60 (4.00), incl	620 (90 000)	485 (70 000)	15	25

[A] Elongation of material 1.6 mm (0.063 in.) greater width (W) shall be measured using a gage length of 50 mm. or 4 W. The gage length must be reported with the test results. The method for determining elongation of material less than 1.6 mm (0.063 in.) in thickness may be negotiated. Alternatively, a gage 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.) Gage length shall be reported with the elongation value.
[B] Applies to plate only.

4.5 *Forging Bar*—Bar as described in 4.4, used for production of forgings, may be furnished in the hot worked condition.

4.6 *Wire*—Rounds, flats, or other shapes less than 4.75 mm (0.1875 in.) in diameter.

4.7 *Other*—Other forms and shapes may be provided by agreement between purchaser and supplier.

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 (sheet, strip, plate, bar, forging bar, or wire),

5.1.4 Condition (see section 6.3),

5.1.5 Mechanical properties (if applicable, for special conditions),

5.1.6 Finish (see section 6.2),

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

5.1.8 Special tests, if any, and

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 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 mechanically descaled or pickled, abrasively blasted, chemically milled, ground, machined, peeled, polished, combinations of these operations, or as specified by the purchaser. 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.

6.3 *Condition*—Material shall be furnished in the annealed or cold-worked condition. Mechanical properties for conditions other than those listed in Table 1 may be established by agreement between the supplier and the purchaser.

7. Chemical Requirements

7.1 The heat analysis shall conform to the chemical composition specified in Table 2. 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 2.

TABLE 2 Chemical Requirements

Element	Composition, % (mass/mass)
Nitrogen, max	0..03
Carbon, max	0.08
Hydrogen, max	0.015
Iron, max	0.25
Oxygen, max	0.15
Aluminum	2.50–3.50
Vanadium	2.00–3.00
Titanium[A]	Balance

[A] The percentage of titanium is determined by difference and need not be determined or certified.

7.1.1 Requirements for the major and minor elemental constituents are listed in Table 2. Also listed are important residual elements. Analysis for elements not listed in Table 2 is not required to verify compliance with this specification.

7.2 *Product Analysis:*

7.2.1 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. The product analysis tolerances shall conform to the product tolerances in Table 3.

7.2.2 The product analysis is either for the purpose of verifying the composition of a heat or manufacturing lot or determining variations in the composition within the heat.

TABLE 3 Product Analysis Tolerance[A]

Element	Tolerance Under the Minimum or Over the Maximum Limit[B] % (mass/mass)
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.0020
Iron	0.10
Oxygen	0.02
Aluminum	0.40
Vanadium	0.15

[A] See AMS 2249.
[B] Under minimum limit not applicable for elements where only a minimum percentage is indicated.

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 3 is 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 E539, E1409, E1447, E1941, and E2371 or other analytical methods agreed upon between the purchaser and the supplier.

7.3 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. 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 1.

8.2 Specimens for tension tests shall be machined and tested in accordance with Test Methods E8/E8M. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 mm/mm/min (in./in./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, Shapes, and Wire*—Test according to Test Methods E8/E8M. Should any test specimen not meet the specified requirements, 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.

8.2.2 Tensile tests results for which any specimen fractures outside the gage length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to subsections 7.11.4 and 7.12.5 of Test Methods E8/E8M. If either the elongation or reduction of area is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements.

8.3 For sheet and strip, the bend test specimen shall withstand being bent cold through an angle of 105° without fracture in the outside surface of the bent portion. The bend shall be made around a mandrel which has a diameter equal to that shown in Table 2. Test conditions shall conform to Test Method E290.

8.3.1 *Sheet, Strip, and Plate*—Test according to Test Methods E8/E8M. Perform at least one tensile test from each lot in both the longitudinal and transverse directions. Tests in the transverse direction need be made only on product from which a specimen not less than 200 mm (8 in.) in length for sheet and 65 mm (2.50 in.) in length for plate can be taken. Should any of these test specimens not meet the specified requirements, 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. Special Requirements

9.1 The microstructure shall be a result of processing within the alpha-plus beta field. Microstructure shall essentially consist of an equiaxed and/or elongated primary alpha in a transformed beta matrix with no continuous alpha network at prior beta grain boundaries.

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 or pickled surface finish. For other products, there shall be no continuous layer of alpha case ≥ 0.0025 mm (≥ 0.001 in.) when examined at 100× magnification.

10. Ultrasonic Inspection

10.1 All centerless ground or peeled and polished round bar ≥ 9.5 mm (0.375 in.) 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 purchaser and supplier.

NOTE 1—AMS 2631 contains varying flat bottom hole (FBH) requirements based on melting grades per AMS 2380. Since the FBH requirements for Class 1 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 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. A report of the test results shall be furnished to the purchaser at the time of shipment.

13. Quality Program Requirements

13.1 The producer shall maintain a quality program as defined in ASQ C1, ISO 9001, or similar quality program.

14. Keywords

14.1 metals (for surgical implants); orthopedic 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 annealed titanium-3aluminum-2.5vanadium alloy to be used in the manufacture of surgical implants.

X1.2 The microstructural requirements contained in this specification represent the current general consensus of opinion 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.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade.

X2.2 No known surgical implant material has ever been shown to be completely free from adverse reactions in the human body. Long-term clinical experience of the use of the material referred to in this specification, however, has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

X2.3 The material in this standard has been subjected to the following studies: MEM elution, colony forming cytotoxicity, sensitization, intracutaneous reactivity – irritation, acute system toxicity, USP implant 7, 30, 60, and 120 days, pyrogencity and the results of all of these tests verified the biocompatibility of the alloy. This material has been used clinically since at least 1995.

ASTM International takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.

This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, at the address shown below.

This standard is copyrighted by ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959, United States. Individual reprints (single or multiple copies) of this standard may be obtained by contacting ASTM at the above address or at 610-832-9585 (phone), 610-832-9555 (fax), or service@astm.org (e-mail); or through the ASTM website (www.astm.org). Permission rights to photocopy the standard may also be secured from the ASTM website (www.astm.org/COPYRIGHT/).