Designation: F2146 – 13

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

This standard is issued under the fixed designation F2146; 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 and annealed or cold-worked and stress-relieved titanium-3aluminum-2.5vanadium alloy (UNS R56320) seamless tubing to be used in the manufacture of surgical implants. See Section 4 for size limitations.

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 from the two systems may result in non-conformance with the standard.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory requirements prior to use.*

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

E1409 Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique

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E2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry (Withdrawn 2013)[3]

E2626 Guide for Spectrometric Analysis of Reactive and Refractory Metals

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)

IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 *Aerospace Material Specifications:*[4]

AMS 2244 Tolerances, Titanium and Titanium Alloy Tubing

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 2634 Ultrasonic Inspection, Thin Wall Metal Tubing

AMS 4943 Titanium Alloy, Seamless, Hydraulic Tubing, 3.0A1-2.5V Annealed

AMS 4944 Titanium Alloy, Seamless, Hydraulic Tubing, 3.0A1-2.5V Cold-Worked, Stress-Relieved

AMS 6940 Titanium Alloy Bars, Forgings, and Forging Stock, 3.0Al-2.5V Annealed-UNS R56320

2.3 *ISO Standards:*[5]

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems Requirements

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

[4] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

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

***A Summary of Changes section appears at the end of this 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 on heating.

3.1.2 *cold work, n*—any mechanical deformation process performed below the recrystallization temperature which results in strain hardening of the material.

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

4. Product Classification

4.1 *Tubing*—Tubular product with an outside diameter greater than 0.250 in. [6.35 mm].

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 (for example, F2146–13),

5.1.3 Form (seamless tubing),

5.1.4 Applicable dimensions including outside diameter, wall thickness, length (exact, random, or multiples), or drawing number,

5.1.5 Finish (see 6.1),

5.1.6 Condition (see 6.2),

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

5.1.8 Special tests (see Section 10), and

5.1.9 Other requirements.

6. Materials and Manufacture

6.1 *Finish*—The mill product shall be furnished to the implant manufacturer as descaled or pickled, abrasive blasted, chemically milled, ground, machined, peeled, polished, or as specified by the purchaser.

6.2 *Condition:*

6.2.1 *Annealed*—Tubing may be annealed by heating to a temperature within the range of 1100 to 1450°F [593 to 788°C], holding at the selected temperature within ±25°F [±14°C] for not less than 15 min, and cooling at a rate equivalent to air cool or slower.

6.2.2 *Cold-Worked and Stress-Relieved*—Tubing may be cold-worked then stress-relieved by heating within the range 700 to 1000°F [371 to 538°C] for not less than 30 min.

6.3 *Surface Cleanliness*—The inside and outside surfaces of the tubing shall be free from grease and other foreign matter. Metallic flakes or particles shall not be collected by a clean, white cloth drawn through the bore of a tube sample. Discoloration of the cloth, without the presence of metallic flakes or particles, is acceptable.

6.4 *Dimensional Tolerances*—All tolerances shall conform to all applicable requirements of AMS 2244, for standard tolerances.

7. Chemical Composition

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 each lot of finished mill product. The number of samples per lot shall be as agreed upon between the supplier and the purchaser. The supplier shall not ship material with a composition outside the requirements specified in Table 1.

7.1.1 Requirements for 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:*

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 between laboratories. The product analysis tolerances shall conform to the product tolerances in Table 2.

7.2.2 The product analysis is 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 analyses 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 supplier and purchaser.

7.2.4 For referee purposes, use Test Methods E1409, E1447, E1941, E2371, and E2626 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 3.

TABLE 1 Chemical Requirements

Element	Composition, % (mass/mass)	
	Minimum	Maximum
Nitrogen	. . .	0.020
Carbon	. . .	0.050
Hydrogen	. . .	0.015
Iron	. . .	0.30
Oxygen	. . .	0.12
Aluminum	2.50	3.50
Vanadium	2.00	3.00
Yttrium	. . .	0.005
Titanium[A]	balance	balance

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

TABLE 2 Product Analysis Tolerances[A]

Element	Tolerance Under the Minimum or Over the Maximum Limit[B]
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.0020
Iron	0.10
Oxygen (up to 0.20)	0.02
Aluminum	0.40
Vanadium	0.15
Yttrium	0.0006

[A] Refer to AMS 2249.
[B] Under the minimum limit not applicable for elements where only a maximum limit is indicated.

TABLE 3 Mechanical Properties[A]

Condition	Ultimate Tensile Strength, min, psi [MPa]	Yield Strength (0.2 %), min, psi [MPa]	Elongation,[B] min, %
Annealed	90 000 [621]	75 000 [517]	15
Cold-worked and stress-relieved	125 000 [862]	105 000 [724]	10[C]

[A] Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and purchaser.
[B] Elongation is based on a 2 in. [50.8 mm] or 4D gauge length for tubing ⅜ in. [9.5 mm] outside diameter or larger, and 1.00 in. [25.4 mm] or 4D gauge length for tubing less than ⅜ in. [9.5 mm] outside diameter and greater than ¼ in. [6.35 mm] outside diameter.
[C] Elongation is 8 % minimum for tubing with wall thicknesses up to 0.016 in. [0.41 mm], inclusive.

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.

8.3 Tensile tests results for which any specimen fractures outside the gauge length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to sections 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.

8.4 *Number of Tests*—Should any test result not meet the specified requirements, two additional samples representative of the same lot shall be tested in the same manner, for each failed test piece. 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:*

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 product certification.

9.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between 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 be a fine dispersion of the alpha and beta phases resulting from processing in the alpha plus beta field. There shall be no continuous alpha network at prior beta grain boundaries. There shall be no coarse, elongated alpha platelets.

10.2 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.

10.3 *Number of Tests*—Examine two samples from each lot on a transverse plane for alpha and beta phases and for alpha case.

10.4 If required by the purchaser, determine the beta transus temperature for each heat by a suitable method and report on the material certification.

10.5 *Ultrasonic Testing:*

10.5.1 Each tube shall be inspected ultrasonically in accordance with AMS 2634 for surface (inside diameter and outside diameter) and subsurface imperfections of all types and orientation (longitudinal and transverse).

10.6 Longitudinal and transverse notches not exceeding 0.010 in. [0.25 mm] in width and 10 % of the nominal tube wall or 0.004 in. [0.102 mm], whichever is greater, in depth shall be machined on the inner and outer surfaces of the tube. The length of the notches shall not exceed 0.125 in. [3.18 mm].

10.7 Any tube showing an indication in excess of that obtained from the calibration standard in accordance with 10.6 shall be set aside and be subject to rework, retest, or rejection. A tube thus set aside may be examined further for confirmation of the presence of a defect and may be resubmitted for inspection if no defect is found. Any tube may also be resubmitted for inspection if reworked so as to remove the defect within the specified diameter and wall thickness tolerances.

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 and met all requirements. 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 ISO 9001.

14. Keywords

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

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the chemical, mechanical, and metallurgical properties of wrought annealed or cold-worked and stress-relieved titanium-3aluminum-2.5vanadium alloy (UNS R56320) seamless tubing to be used in the manufacture of surgical implants.

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

X1.4 This alloy is similar in microstructure to both titanium-6aluminum-4vanadium ELI (Specification F136) and titanium-6aluminum-4vanadium (Specification F1472), but is not as highly alloyed as either of these two titanium alloys.

X1.5 This alloy has also been characterized for aerospace and industrial applications, and exhibits similar mechanical properties to titanium alloys used in load-bearing orthopedic implant applications. Published standards include: AMS 4943, AMS 4944, and AMS 6940.

X1.6 This alloy has also been used commercially in medical and surgical devices for over a decade.[6]

X1.7 ISO standards are listed for reference only. Although ISO 6892 listed in 2.3 is similar to the corresponding ASTM standard, it is not identical. Use of the ISO standard instead of the preferred ASTM standard (Test Methods E8/E8M) may be agreed upon between the purchaser and supplier.

X1.8 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 material 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] FDA 510K Application Number K926232, submitted by Howmedica, Inc., Rutherford, NJ.

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, exhibiting a well-characterized level of biological response, for over a decade.

X2.2 No known surgical implant material has ever been shown to be completely free of 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 specification has been subjected to animal studies and has been shown to produce a well-characterized level of biological response that is equal to or less than that produced by the reference material titanium. This material has been used clinically for over a decade.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F2146–07) that may impact the use of this standard.

(1) Updated form and structure to comply with the current Titanium template.
(2) Added clarification of SI units in Section 1.2, 9, and other sections where appropriate.
(3) Deleted reference to ASQ C1.
(4) Added E1941 to 7.2.4.
(5) Removed "since 1983" and changed to "for over a decade" in X2.3.
(6) Changed "machined" to "prepared" in 8.2.