Designation: F2146 – 22

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, and values from the two systems shall not be combined.

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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *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:*[2]

B367 Specification for Titanium and Titanium Alloy Castings

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 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)[3]

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

[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 Jan. 1, 2022. Published January 2022. Originally approved in 2001. Last previous edition approved in 2013 as F2146 – 13. DOI: 10.1520/F2146-22.

[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**

ISO 9001 Quality Management Systems Requirements
ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

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 6.35 mm [0.250 in.].

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, F2146–22),

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 593 to 788 °C [1100 to 1450 °F], holding at the selected temperature within ±14 °C [±25 °F] 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 of 371 to 538 °C [700 to 1000 °F] 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 supplier's heat analysis shall conform to the chemical composition prescribed in 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.

7.1.2 All commercial metals may contain small amounts of elements other than those which are specified. It is neither practical nor necessary to specify limits for unspecified elements that can be present. The supplier/producer is permitted to analyze for unspecified elements and is permitted to report such analyses. The presence of an unspecified element and the reporting of an analysis for that element shall not be a basis for rejection unless previously agreed to between supplier and purchaser.

7.1.3 Intentional elemental additions other than those specified in Table 1 are not permitted.

7.1.4 Analysis for elements not listed in Table 1 is not required to verify compliance with this specification.

7.1.5 Methods and practices relating to chemical analysis required by this specification shall be tested in accordance with Test Methods E1409, E1447, E1941, E2371, and Guide E2626.

7.2 *Product (Check) Analysis:*

7.2.1 The product (check) 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

TABLE 1 Chemical Requirements, Heat Analysis

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
Cobalt	. . .	<0.1 %
Other elements each[B]	. . .	0.10
Other elements total	. . .	0.4
Titanium[A]	balance	balance

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

[B] Other elements need not be reported unless the concentration level is greater than 0.1 % each, or 0.4 % total. Other elements may not be added intentionally. Other elements may be present in titanium or titanium alloys in small quantities and are inherent to the manufacturing process. In titanium these elements typically include aluminum, vanadium, tin, chromium, molybdenum, niobium, zirconium, hafnium, bismuth, ruthenium, palladium, yttrium, copper, silicon, cobalt, tantalum, nickel, boron, manganese, and tungsten.

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
Cobalt	0.02[C]

[A] Refer to AMS 2249.
[B] Under the minimum limit not applicable for elements where only a maximum limit is indicated.
[C] Refer to Specification B367, Table 2 "Other (Each)."

TABLE 3 Mechanical Properties[A]

Condition	Ultimate Tensile Strength, min, MPa [psi]	Yield Strength (0.2 %), min, MPa [psi]	Elongation,[B] min, %
Annealed	621 [90 000]	517 [75 000]	15
Cold-worked and stress-relieved	862 [125 000]	724 [105 000]	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 50.8 mm [2 in.] or 4D gauge length for tubing 9.5 mm [⅜ in.] outside diameter or larger, and 25.4 mm [1.00 in.] or 4D gauge length for tubing less than 9.5 mm [⅜ in.] outside diameter and greater than 6.35 mm [¼ in.] outside diameter.
[C] Elongation is 8 % minimum for tubing with wall thicknesses up to 0.41 mm [0.016 in.], inclusive.

ingot) analysis requirements but cover variations between laboratories in the measurement of chemical content.

7.2.2 Product (check) analysis limits are not for supplier's/producer's use at supplier's/producer's acceptance testing. Product analysis tolerances are not permitted to be applied to ladle or ingot analysis. The supplier/producer shall not ship material that is outside the limits specified in Table 1.

7.2.3 A product (check) analysis is one performed by 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 fabricating techniques employed (for example oxygen, nitrogen, hydrogen) unless the sample is sufficiently large to produce a reliable result.

7.2.4 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 (check) 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.

7.2.5 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 ability to react with elements such as oxygen, nitrogen, and hydrogen. Therefore, when cutting samples for analysis, 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.

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

8. Mechanical Requirements

8.1 The material supplied under this specification shall conform to the mechanical property requirements in Table 3.

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 0.076 to 0.178 mm/mm/min [0.003 to 0.007 in./in./min] through yield and then the crosshead speed may be increased so as to produce fracture in approximately one additional minute.

8.3 Tensile test 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 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.

8.4 *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 the purchaser and the 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 of IEEE/ASTM SI 10 provides conversion tables and Annex B of IEEE/ASTM SI 10 provides rules for conversion and significant digits.