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E2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry (Withdrawn 2013)[3]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