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.

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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**

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.