



Designation: F 2146 – 01

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 F 2146; 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 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 3 for size limitation.

1.2 The values stated in inch pound units are to be regarded as the standard. The SI equivalents in parentheses are for information only.

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:

- E 8 Test Methods for Tension Testing of Metallic Materials²
- E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys³
- E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique⁴
- E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method⁴
- F 136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications⁵
- F 1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy (UNS R56400) for Surgical Implant Applications⁵

2.2 Aerospace Material Specifications:

- AMS 2244 Tolerances, Titanium and Titanium Alloy Tubing⁶
- AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys⁶
- AMS 2634 Ultrasonic Inspection, Thin Wall Metal Tubing⁶
- AMS 4943 Titanium Alloy, Seamless, Hydraulic Tubing, 3.0A1-2.5V Annealed⁶
- AMS 4944 Titanium Alloy, Seamless, Hydraulic Tubing, 3.0A1-2.5V Cold-Worked, Stress-Relieved⁶

2.3 ANSI Publication:

- ANSI/ASME B46.1 Surface Texture, Surface Roughness Waviness and Lay⁷

2.4 American Society for Quality Standard:

- ASQ C1 Specifications of General Requirements for a Quality Program⁸

2.5 Military Standard:

- MIL-T-9047 Titanium and Titanium Alloy Bars (Rolled or Forged) and Reforging Stock, Aircraft Quality⁹

3. Classification

- 3.1 *Tubing*—Round product with an outside diameter greater than 0.250 in. (6.35 mm).

4. Ordering Information

4.1 Include with inquiries and orders for material under this specification the following information:

- 4.1.1 Quantity,
- 4.1.2 ASTM designation and date of issue,
- 4.1.3 Form (seamless tubing),
- 4.1.4 Condition (see 5.1),
- 4.1.5 Mechanical properties (if applicable, for special conditions),

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 *Annual Book of ASTM Standards*, Vol 03.01.

³ *Annual Book of ASTM Standards*, Vol 03.05.

⁴ *Annual Book of ASTM Standards*, Vol 03.06.

⁵ *Annual Book of ASTM Standards*, Vol 13.01.

⁶ Available from Society of Automotive Engineers, Inc., 400 Commonwealth Dr., Warrendale, PA 15096-0001.

⁷ Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY, 10036.

⁸ Available from American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

⁹ Available from Standardization Documents Order Desk, Bldg. 4, Section D, 700 Robbins Ave., Philadelphia, PA 19111-5098, Attn: NPODS.

4.1.6 Finish (see 5.2),

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

4.1.8 Special tests (see 8.1-8.3), and

4.1.9 Other requirements.

5. Materials and Manufacture

5.1 Condition:

5.1.1 *Annealed*—Tubing may be annealed by heating to a temperature within the range 1100 to 1450°F (593 to 788°C), holding at the selected temperature within $\pm 25^\circ\text{F}$ ($\pm 14^\circ\text{C}$) for not less than 15 min, and cooling at a rate equivalent to air cool or slower.

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

5.2 *Finish*—Material surfaces will be furnished in accordance with the customer order, which may include pickling, polishing, or grit blasting, or a combination of these operations.

5.3 *Surface Cleanliness*—The inside diameter and outside diameter 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.

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

6. Chemical Composition

6.1 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 outside the requirements specified in Table 1.

6.1.1 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.

6.2 *Product Analysis*—Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemi-

cal content. The manufacturer shall not ship material that is outside the limits specified in Table 1. The product analysis tolerances shall conform to the product tolerances in Table 2.

6.2.1 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.

6.2.2 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product analysis.

6.3 For referee purposes, use Test Methods E 120, E 1409, and E 1447 or other analytical methods agreed upon between the purchaser and the supplier.

6.4 Ensure that the samples for chemical analysis are 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.

7. Mechanical Properties

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

7.2 Specimens for tension tests shall be machined and tested in accordance with Test Methods E 8. 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.

7.3 *Number of Tests*—Perform a minimum of two tension tests from each lot. A lot is defined as the total number of mill products produced under the same conditions at essentially the same time from the same heat. If both test specimens fail, the lot is unacceptable. Should either of the two test specimens not meet the specified requirements, test two additional test pieces representative of the same lot in the same manner. The lot will be considered in compliance only if both additional test pieces meet the specified requirements. If a specimen fails outside the gage, the test is null in accordance with Test Methods E 8, and a retest shall be performed.

8. Special Tests

8.1 Each tube shall be ultrasonically inspected in accordance with AMS 2634 for surface (inside diameter and outside

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 or certified.

TABLE 2 Product Analysis Tolerance^A

Element	Tolerance Under the Minimum or Over the Maximum Limit as Listed in Table 1 (Composition, % mass/mass) ^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.