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Standard Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700)¹

This standard is issued under the fixed designation F1295; 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 reappraisal. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reappraisal.

1. Scope*

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought annealed, cold-worked, or hot-worked titanium-6aluminum-7niobium alloy bar, wire, sheet, strip, and plate to be used in the manufacture of surgical implants **(1-7)**.²

1.2 The SI units in this standard are the primary units. The values stated in either primary SI units or secondary 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 nonconformance 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, 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:³

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

E290 Test Methods for Bend Testing of Material for Ductility

E539 Test Method for Analysis of Titanium Alloys by Wavelength Dispersive X-Ray Fluorescence Spectrometry

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 Reactive Metals and Reactive Metal Alloys by Inert Gas Fusion with Detection by Thermal Conductivity or Infrared Spectrometry

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)

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 The boldface numbers in parentheses refer to a list of references at the end of the text.

³ 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.

*A Summary of Changes section appears at the end of this standard

E2626 Guide for Spectrometric Analysis of Reactive and Refractory Metals (Withdrawn 2017)⁴

E2994 Test Method for Analysis of Titanium and Titanium Alloys by Spark Atomic Emission Spectrometry and Glow Discharge Atomic Emission Spectrometry (Performance-Based Method)

IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 *Aerospace Material Specification*:⁵

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 2630 Inspection, Ultrasonic Product Over 0.5 Inch (12.7 mm) Thick

AMS 2631 Ultrasonic Inspection—Titanium and Titanium Alloy Bar and Billet

2.3 *ISO Standards*:⁶

ISO 5832-11 Implants for Surgery—Metallic Materials—Part 11: Wrought Titanium 6-Aluminum 7-Niobium Alloy

ISO 6892-1 Metallic Materials—Tensile Testing—Part 1: Method of Test at Room Temperature

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.

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

3.1.3 *hot work*—any mechanical deformation process performed above the recrystallization temperature.

3.1.4 *lot, n*—the total number of mill products produced from the same melt heat under the same conditions at essentially the same time.

3.1.5 *stress relief*—thermal treatment that reduces the residual stresses in the material without affecting the mechanical properties.

4. Product Classification

4.1 *Bar*—Round, rectangular, or other complex shaped product delivered straightened and cut to defined lengths.

4.2 *Forging Bar*—Bar as described in 4.1, used in the production of forgings. This product may be furnished in the hot-worked condition.

4.3 *Wire*—Round, rectangular, or other complex shapes of uniform cross section along its entire length furnished in coils, or on spools, reels, or other packaging as specified.

4.4 *Strip*—Any product 4.76 mm [0.188 in.] and under in thickness and less than 610 mm [24 in.] in width.

4.5 *Sheet*—Any product 4.76 mm [0.188 in.] and under in thickness and 610 mm [24 in.] or more in width.

4.6 *Plate*—Any product 4.76 mm [0.188 in.] thick and over 254 mm [10 in.] wide and over, with widths greater than five times thickness. Plate up to 101.60 mm [4 in.] thick, inclusive, is covered by this specification.

5. Ordering Information

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

5.1.1 Quantity (weight or number of pieces),

⁴ The last approved version of this historical standard is referenced on www.astm.org.

⁵ Available from SAE International (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, <http://www.sae.org>.

⁶ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

- 5.1.2 Applicable ASTM designation, date of issue,
- 5.1.3 Form (bar, wire, sheet, strip, or plate),
- 5.1.4 Condition (see 6.2),
- 5.1.5 Mechanical properties (if applicable for special conditions),
- 5.1.6 Finish (see 6.1),
- 5.1.7 Applicable dimensions including size, thickness, width, or drawing number,
- 5.1.8 Special tests, if any, and
- 5.1.9 Other requirements.

6. Materials and Manufacture

6.1 *Finish*—The mill product may be supplied as specified by the purchaser with a descaled or pickled, abrasive-blasted, chemically milled, ground, machined, peeled, or polished finish.

6.2 *Condition*—Material shall be furnished in the annealed, cold-worked, or hot-worked condition. The purchaser shall include on drawings or purchase orders whether the material shall be stress-relieved.

7. Chemical Requirements

7.1 The supplier's heat analysis shall conform to the chemical composition of **Table 1**. The supplier shall not ship material with chemistry outside the requirements specified in **Table 1**. Ingot analysis may be used for reporting all chemical requirements, except hydrogen. Samples for hydrogen shall be taken from the finished mill product.

7.1.1 Requirements for the major and minor elemental constituents are listed in **Table 1**. Also listed are important residual elements.

TABLE 1 Chemical Requirements

Element	Composition, %
Aluminum	5.50 to 6.50
Niobium	6.50 to 7.50
Tantalum	0.50 max
Iron	0.25 max
Oxygen	0.20 max
Carbon	0.08 max
Nitrogen	0.05 max
Hydrogen	0.009 max
Cobalt ^A	<0.10
Cobalt	<0.10
Other elements each ^B	0.10 max
Other elements each ^A	0.10 max
Other elements total	0.4 max
Titanium ^C	Balance
Titanium ^B	Balance

^A Refer to X1.8.

^A 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.

^B The percentage of titanium is determined by difference and need not be determined or certified.

7.1.2 All commercial metals may contain small amounts of elements other than those which are specified in **Table 1**. It is neither practical nor necessary to specify limits for unspecified elements that can be present. The 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 purchaser and supplier.

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 certify 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 **E539**, **E1409**, **E1447**, **E1941**, **E2371**, and **E2994**, and Guide **E2626**.

7.2 *Product (Check) Analysis*—The product (check) analysis tolerances shall conform to the product tolerances in **Table 2** per AMS 2249. Product (check) analysis tolerances do not broaden the specified heat (ladle or ingot) analysis requirements but cover variations between laboratories in the measurement of chemical content.

7.2.1 Product (check) analysis limits are not for 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 shall not ship material that is outside the limits specified in **Table 1**.

7.2.2 A product (check) analysis is one performed by the purchaser or supplier of the metal after it has been worked into one of the forms specified in Section 4, and 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 (check) analysis. Product (check) analysis outside the tolerance limits allowed in **Table 2** are cause for rejection of the product. A referee analysis may be used if agreed by supplier and purchaser.

7.3 For referee purposes, use Test Methods **E539**, **E1409**, **E1447**, **E1941**, **E2371**, and **E2994**, and Guide **E2626** or other analytical methods agreed upon between the purchaser and the supplier.

7.4 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. 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 properties given in **Table 3**. Alternative properties may be agreed upon between the purchaser and supplier.

TABLE 2 Product Analysis Tolerances^A

Tolerance Under the Minimum ^B or Over the Maximum Limit (%)	
Aluminum	0.40
Niobium	0.20 under min 0.25 over max
Tantalum	0.10
Iron	0.10
Oxygen	0.02
Carbon	0.02
Nitrogen	0.02
Hydrogen	0.002
Cobalt ^C	0.02

^A Refer to AMS 2249.

^B Under minimum limit not applicable for elements where only a maximum percentage is indicated.

^C Refer to Specification **B367**, Table 2 “Other (Each).”