Designation: F1295 – 16

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 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, cold-worked, or hot-worked titanium-6aluminum-7niobium alloy bar, wire, sheet, strip, and plate to be used in the manufacture of surgical implants (**1-4**).[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 non-conformance with the standard.

2. Referenced Documents

2.1 *ASTM Standards:*[3]

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

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

IEEE/ASTM SI 10 American National Standard for Use of the International System of Units (SI): The Modern Metric System

2.2 *Aerospace Material Specification:*[4]

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:*[5]

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

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

3.1.4 *hot work*—any mechanical deformation process performed above the recrystallization 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] 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.

[4] Available from SAE International (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**

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

4. Product Classification

4.1 *Bar*—Rounds, or flats, or other shapes from 0.188 in. (4.76 mm) to 4.0 in. (102 mm) in diameter or thickness. Other sizes and shapes by special order.

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*—Rounds, flats, or other shapes less than 0.188 in. (4.76 mm) in diameter or thickness.

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

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

4.6 *Plate*—Any product 0.188 in (4.76 mm) thick and over 10 in. (254 mm) wide and over, with widths greater than five times thickness. Plate up to 4 in. (101.60 mm), 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),

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,

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 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 the finished mill product. The supplier shall not ship material with chemistry outside the requirements specified in Table 1.

7.1.1 Requirements for the 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 certify compliance with this specification.

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
Titanium[A]	Balance

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

7.2 *Product Analysis:*

7.2.1 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations 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 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 E1409, E1447, E1941, E2371, and 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 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.

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

[A] Refer to AMS 2249.

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

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.

8.2 Specimens for tension tests shall be machined and tested in accordance with Test Methods E8/E8M. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in./min (mm/mm/min) through the specified yield and then the crosshead speed shall be increased so as to produce fracture in approximately one additional minute.

8.2.1 *Bar, Forging Bar, and Wire*—Test according to Test Methods E8/E8M.

8.2.2 Tensile tests result for which any specimen fractures outside the gauge length shall be considered valid, if both the elongation and reduction of area meet the minimum requirements specified. If either the elongation or reduction of area is less than the minimum requirement, invalidate the specimen and retest. Retest one specimen for each invalidated specimen.

8.2.3 Should any test specimen not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test specimen. The lot will be considered in compliance only if all additional test pieces meet the specified requirements.

8.3 *Sheet, Strip, and Plate:*

8.3.1 Test according to Test Methods E8/E8M. Perform at least one tensile test from each lot in both the longitudinal and transverse directions. Tests in the transverse direction need be made only on product from which a specimen not less than 8.0 in. (200 mm) in length for strip can be taken. Should any of these test specimens not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test specimen. The lot will be considered in compliance only if all additional test pieces meet the specified requirements.

8.3.2 For sheet and strip, the bend test specimen shall withstand being bent cold through an angle of 105° without fracture in the outside surface of the bent portion. The bend shall be made around a mandrel which has a diameter equal to that shown in Table 4. Test conditions shall conform to Test Method E290.

9. Dimensions and Permissible Variations

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 purchaser and 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.

10. Special Requirements

10.1 The microstructure shall be a fine dispersion of the alpha and beta phases resulting from processing in the alpha plus beta field. There shall be no continuous alpha network at prior beta grain boundaries. There shall be no coarse, elongated alpha platelets.

10.2 Determine the beta transus temperature for each heat by a suitable method and report on the material certification if required by the purchaser.

10.3 Alpha case is not permitted for products supplied with a machined, ground, or chemically milled surface finish. For other products, there shall be no continuous layer of alpha case when examined at 100× magnification.

11. Ultrasonic Inspection

11.1 For finished thicknesses 0.250 in. (6.35 mm) and greater, inspection shall be per AMS 2631 Class A1 for bar and billet or per AMS 2630 Class A1 for product forms not covered

TABLE 3 Mechanical Properties for Bar and Wire

Condition[A]	Ultimate Tensile Strength, min, MPa (psi)	Yield Strength (0.2 % Offset), min, MPa (psi)	Elongation,[B] min, %	Reduction of Area, min, %
Annealed	900 (130 500)	800 (116 000)	10	25
Hot Worked	900 (130 500)	800 (116 000)	10	25
Cold Worked	1100 (159 500)	800 (116 000)	10	25

[A] Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and purchaser.

[B] Elongation of material 1.6 mm (0.063 in.) or greater in diameter (D) or thickness (T) shall be measured using a gauge length of 2 in. or 4D or 4W. The gauge length must be reported with the test results. The method for determining elongation of material under 1.6 mm (0.063 in.) in diameter or thickness may be negotiated. Alternatively, a gauge length of 5.65 times the square root of So, where So is the original cross-sectional area corresponding to ISO 6892–1 may be used when agreed upon between supplier and purchaser.

TABLE 4 Mechanical Properties for Sheet, Strip, and Plate

Condition[A]	Ultimate Tensile Strength min, MPa (psi)	Yield Strength (0.2 % offset), min, MPa (psi)	Elongation[B] in 50 mm (2 in.), min %	Bend Test Mandrel Diameter[C]	
				Under 1.78 mm (0.070 in.) in Thickness	1.78 to 4.76 mm (0.070 to 0.188 in.) in Thickness
Annealed	900 (130 500)	800 (116 000)	10	9T	10T

[A] Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and purchaser.
[B] Elongation of material 1.6 mm (0.063 in.) or greater in thickness shall be measured using a gauge length of 50 mm (2 in.). The gauge length must be reported with the test results. The method for determining elongation of material under 1.6 mm (0.063 in.) in thickness may be negotiated. Alternatively, a gauge length corresponding to ISO 6892–1 may be used when agreed upon between supplier and purchaser. (5.65 times the square root of So, where So is the original cross sectional area.) Gauge length will be reported with the elongation value.
[C] T equals the thickness of the bend test specimen. Bend tests are not applicable to material over 4.76 mm (0.188 in.) in thickness. The limits listed apply to tests taken both longitudinal and transverse to the direction of rolling.

by AMS 2631. Equivalent test methods may be substituted when agreed to by purchaser and supplier.

11.2 For finished thicknesses less than 0.250 in. (6.35 mm) and for product that cannot be inspected at finish, intermediate size bar, slab, or billet shall be ultrasonically inspected per AMS 2631 Class A1, per AMS 2630 Class A1 for product forms not covered by AMS 2631, or as agreed upon by purchaser and supplier.

12. Significance of Numerical Limits

12.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right hand digit used in expressing the specification limit, in accordance with the Rounding Method of Practice E29.

13. Certification

13.1 The supplier shall provide certification that the material was tested in accordance with this specification and met all requirements. A report of the test results shall be furnished to the purchaser at the time of shipment.

14. Quality Program Requirements

14.1 The supplier shall maintain a quality program as defined in ISO 9001 or similar quality program.

15. Keywords

15.1 metals (for surgical implants); orthopaedic medical devices; titanium alloys (for surgical implants)

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the composition and properties of wrought annealed, cold-worked, or hot-rolled Ti-6A1-7Nb titanium alloy bar and wire to ensure consistency in the starting material used in the manufacture of medical devices, in particular of surgical implants.

X1.2 The microstructural requirements contained in this specification represent the current general consensus of opinion with respect to optimization of mechanical properties for implant applications.

X1.3 The minimum mechanical properties specified ensure a baseline of strength and ductility for the highly stressed devices that may be manufactured from this alloy.

X1.4 The stress corrosion cracking resistance of this alloy is similar to Ti-6A1-4V alloy.

X1.5 The UNS designation has been added, residual element language has been included, alpha case information has been clarified, the inclusion requirement has been deleted because no standard method exists for determining the inclusion content in titanium alloys, and Appendix X2 Biocompatibility section has been added to the Rationale.

X1.6 ISO standards are listed for reference only. Although ISO 5832-11 listed in 2.3 is similar to the corresponding ASTM standards, they are not identical. Use of the ISO standards in addition to or instead of the preferred ASTM standard may be negotiated between the purchaser and supplier.

X1.7 The various titanium mill products covered in this specification normally are formed with the conventional forging and rolling equipment found in primary ferrous and nonferrous plants. The material is usually multiple melted in arc furnaces (including furnaces such as plasma arc and electron beam) of a type conventionally used for reactive metals.

X1.8 *Units of Measure*:

X1.8.1 *ASTM Policy*—ASTM is promoting the use of rationalized SI (metric) units in their standards. The F12.04

Committee has modified this specification to facilitate the transition by the medical materials industry to SI between now and 2018. In the first phase of this transition, running to 2013, the specifications will be structured to allow the use of either SI or inch-pound units. The choice of primary units in each specification will be determined by the industry using the specification. The change to SI units during this period may be initiated by the purchaser through his purchase documentation. In the second phase of this transition the specifications will be written with SI as the primary units. Harmonization with corresponding ISO documents should be considered when assigning the SI values.

X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this specification has been employed successfully in contact with soft tissue and bone for over a decade.

X2.2 No known surgical implant has ever been shown to be completely free of adverse reactions in the human body. However, long-term clinical experience has shown an acceptable level of biological response can be expected, if the material is used in appropriate applications.

X2.3 The material in this specification has been subjected to animal studies (**5**) and has been shown to produce a well characterized level of biological response that is equal to or less than that produced by the reference material titanium. This material has been used clinically since 1986 (**6, 7**).

REFERENCES

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(6) Semlitsch, M., "Titanium Alloys for Hip Joint Replacements," *Clinical Materials*, 2, 1987, pp. 1–13.

(7) Zweymüller, K. A., Lintner, F. K., and Semlitsch, M. F., "Biologic Fixation of a Press-Fit Titanium Hip Joint Endoprosthesis," *Clinical Orthopaedics and Related Research* 235, Oct. 1988, pp. 195–206.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F1295–11) that may impact the use of this standard. (Approved October 1, 2016.)

(1) Scope 1.2, Table 3, and Table 4 were changed to include SI as the primary units.

(2) ISO Standard ISO 6892 was changed to ISO 6892–1.

(3) Incorrect product analysis tolerances for aluminum and niobium in Table 2 were corrected to match AMS 2249 and % units added to Table 2.

(4) Yield strength (0.2 % offset) of minimum 130,500 psi (900 MPa) was corrected to minimum 800 MPa (116,000 psi) in Table 4.

(5) Editorial corrections have been made in order to meet terminology and formatting guidelines established for implant material standards within F04.12.