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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 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 rolled~~ hot-worked titanium-6aluminum-7niobium alloy bar, wire, sheet, strip, and ~~wire~~plate to be used in the manufacture of surgical implants **(1-4)**.[2]

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

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.

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E8~~8~~/E8M Test Methods for Tension Testing of Metallic Materials

E~~120~~~~Test Methods for Chemical Analysis of Titanium and Titanium Alloys~~ 29 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 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

~~F981Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone~~

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

E2626 Guide for Spectrometric Analysis of Reactive and Refractory Metals

SI 10 American National Standard for Use of the International System of units (SI): The Modern Metric System

2.2 ~~*ISO Standards:*~~

~~ISO5832–11Implants for Surgery—Metallic Materials—Part 11: Wrought Titanium 6–Aluminum 7–Niobium Alloy~~

~~ISO 6892 Metallic Materials—Tensile Testing~~

~~2.3 *Aerospace Material Specification:*~~[4]

AMS 2249~~Chemical Check Analysis Limits, Titanium and Titanium Alloys~~

~~2.4 *American Society for Quality Standard:*~~

~~ASQC1Specification of General Requirements for a Quality Program~~ Chemical Check Analysis Limits, Titanium and Titanium Alloys

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

[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.

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

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 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.

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

4. Product Classification

~~3.1*bar*—rounds or flats from 0.1875 to 4 in. (4.76 to 101.60 mm) in diameter or thickness. Other sizes and shapes by special order.~~

~~3.2*forging bar*—bar as described in 3.1, used for the production of forgings, may be furnished in the hot rolled condition.~~

~~3.3*wire*—rounds or flats less than 0.1875 in. (4.76 mm) in diameter or thickness.~~

~~4.~~

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

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

~~4.1.1Quantity (weight or number of pieces),~~

~~4.1.2Applicable ASTM designation, date of issue.~~

~~4.1.3Form (bar or wire),~~

~~4.1.4Condition (see 5.3~~

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),

~~4~~5.1.5 Mechanical Properties (if applicable for special conditions),

~~4~~5.1.6 Finish (see ~~5.2~~6.1),

~~4~~5.1.7 Applicable dimensions including size, thickness, width, or drawing number,

~~4~~5.1.8 Special tests, if any,

~~4~~5.1.9 Other requirements.

~~5.~~6. Materials and Manufacture

~~5.1The 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 alloy is usually multiple melted in arc furnaces (including furnaces such as plasma arc and electron beam) of a type conventionally used for reactive metals.~~

~~5.2~~

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

6.1 *Finish*—The mill product may be furnished to the implant manufacturer as descaled or pickled, sandblasted, chemically milled, ground, machined, peeled, polished, cold drawn, or as specified by the purchaser.

5.3—*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 rolled condition.

6.—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

6.1The7.1 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 limitsrequirements specified in Table 1.

67.1.1 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.

6.2

7.2 *Product Analysis*:

6.2.1Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. The manufacturer shall not ship material that is outside the limits specified in Table 1. The product analysis tolerances shall conform to

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.

6.2.2The 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.

6.2.3Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product analysis tolerance.

6.3For referee purposes, use Test Methods E120.

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, and , E1447, E1941, E2371, and E2626 or other analytical methods agreed upon between the purchaser and the supplier.

6.4Ensure that the samples 7.4 Samples for chemical analysis are 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.

7.8. Mechanical Requirements

7.1The8.1 The material supplied under this specification shall conform to the mechanical properties given in Table 3.

7.2Specimens for tension tests shall be machined and tested in accordance with Test Methods E8. 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.

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.