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Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)[1]

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ε^1 NOTE—Editorially corrected the ISO 5832–3 designation throughout in December 2008.

1. Scope*

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought annealed titanium-6aluminum-4vanadium alloy (UNS R56400) to be used in the manufacture of surgical implants.

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

1.2 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E 8 Test Methods ~~of~~for Tension Testing of Metallic Materials

~~E120Test Methods for Chemical Analysis of Titanium and Titanium Alloys~~ E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E 290 Test Method~~s~~ for Bend Testing of ~~Materials~~Material for Ductility

E 527~~Practice for Numbering Metals and Alloys (UNS)~~ Practice for Numbering Metals and Alloys in the Unified Numbering System (UNS)

E 1409 Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique

E 1447~~Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method~~

~~F981Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone~~ Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity/Infrared Detection Method

E 2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry

2.2 *ASQ Standard:*[3]

ASQ C1 Specifications of General Requirements for a Quality Program

[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* ~~, Vol 03.01.~~volume information, refer to the standard's Document Summary page on the ASTM website.

~~[3] Annual Book of ASTM Standards, Vol 03.05.~~

[3] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

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

2.3 *Aerospace Material Specifications:*[4]
AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys
AMS 4911 Titanium Alloy Sheet, Strip, and Plate 6Al-4V Annealed
AMS 4928 Titanium Alloy Bars, Wire, Forgings, Rings, and Drawn Shapes 6Al-4V Annealed
AMS 4965 Titanium Alloy, Bars, Wire, Forgings, and Rings 6.0Al-4.0V Solution Heat Treated and Aged
2.4 ~~*Society of Automotive Engineers Standard:*~~ *ISO Standards:*[5]
ISO 5832–3 Implants for Surgery—Metallic Materials—Part 3, Wrought Titanium-6Aluminum-4Vanadium Alloy
ISO 9001 Quality Management Systems—Requirements
2.5 *Society of Automotive Engineers Standard:*[4, 6]
SAE J1086 Practice for Numbering Metals and Alloys (UNS)

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*
3.2 *lot*, *n*—the total number of mill products produced from one heat under the same conditions at essentially the same time.

4. Product Classification

4.1 *Strip*—Any product under ~~0.1875~~0.188 in. (~~4.75~~4.76 mm) in thickness and under 24 in. (610 mm) wide.
4.2 *Sheet*—Any product under ~~0.1875~~0.188 in. (~~4.75~~4.76 mm) in thickness and 24 in. (610 mm) or more in width.
4.3 *Plate*—Any product ~~0.1875~~0.188 in. (~~4.75~~4.76 mm) thick and over and 10 in. (254 mm) wide and over, with widths greater than five times thickness. Plate up to 4.00 in. (~~101.60~~102 mm) thick, inclusive, is covered by this specification.
4.4 *Bar*—Round bars and flats from ~~0.1875~~0.188 in. (~~4.75~~4.76 mm) to 4.00 in. (~~101.60~~102 mm) in diameter or thickness (other sizes and shapes by special order).
4.5 *Forging Bar*— Bar as described in 4.4~~, used for production of forgings, may be furnished in the hot rolled condition.~~ , used in the production of forgings. This product may be furnished in the hot worked condition.
4.6 *Wire*—~~Rounds or flats less than 0.1875 in. (4.75 mm) in diameter.~~ —Rounds, flats, or other shapes less than 0.188 in. (4.76 mm) in diameter or thickness.

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,
~~5.1.3Form (sheet, strip, plate, bar, or wire),~~
5.1.3 Form (strip, sheet, plate, bar, forging bar, or wire),
5.1.4 Condition (see 6.3),
5.1.5 Mechanical properties (if applicable, for special conditions),
5.1.6 Finish (see 6.2),
5.1.7 Applicable dimensions including size, thickness, width, length, or drawing number,
5.1.8 Special tests, if any, and
5.1.9 Other requirements.

6. Materials and Manufacture

6.1 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 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.
6.2 *Finish*—~~The mill product may be furnished to the purchaser as mechanically descaled or pickled, sandblasted, chemically milled, ground, machined, peeled, polished, combinations of these operations, or as specified by the purchaser.~~ —The mill product may be furnished to the purchaser as mechanically descaled or pickled, sandblasted, chemically milled, ground, machined, peeled, polished, combinations of these operations, or as specified by the purchaser. On billets, bars, plates, and forgings, it is permissible to remove minor surface imperfections by grinding if the resultant area meets the dimensional and surface finish requirements of this specification.
6.3 *Condition*—Material shall be furnished in the annealed or cold-worked condition.

~~[4] Annual Book of ASTM Standards, Vol 01.01.~~
[4] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.
~~[5] Annual Book of ASTM Standards, Vol 03.06.~~
[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.
~~[6] Annual Book of ASTM Standards, Vol 13.01.~~
[6] New designation established in accordance with E 527 and SAE J1086.

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. 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 verify compliance with this specification.

7.2 *Product Analysis*—~~Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. The supplier shall not ship material that is outside the limits specified in Table 1. The product analysis tolerances shall conform to the product tolerances in~~ :

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.

~~7.2.1The 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.~~

~~7.2.2Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product analysis.~~

~~7.2.3For referee purposes, use Test Methods E120, E1409, and E1447~~

7.2.2 The product analysis is either for the purpose of verifying the composition of a heat or manufacturing lot or for determining 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 analyses outside the tolerance limits allowed in Table 2 are cause for rejection of the product. A referee analysis may be used if agreed upon by supplier and purchaser.

7.2.4 For referee purposes, use Test Methods E 1409, E 1447, and E 2371 or other analytical methods agreed upon between the purchaser and the supplier.

~~7.3Ensure that the samples~~ 7.3 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.

8. Mechanical Requirements

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

~~8.2Specimens 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 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.

8.3 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~~over a mandrel ~~that has~~with a diameter equal to that shown in Table 3. Test conditions shall conform to Test Method E 290.

8.4 *Number of Tests*:

8.4.1 *Bar, Forging Bar, Shapes, and Wire*—~~ Perform at least one tension test from each lot. 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 both additional test pieces meet the specified requirements.~~

~~8.4.2~~— *Perform at least one tension test from each lot in the longitudinal direction. 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 both additional test pieces meet the specified requirements.*

TABLE 1 Chemical Requirements[A]

Element	Composition, %
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max[B]	0.015
Iron, max	0.30
Oxygen, max	0.20
Aluminum	5.5–6.75
Vanadium	3.5–4.5
Yttrium, max	0.005
Titanium[C]	balance

[A] Refer to AMS 4928.

[B] Billets shall have a maximum of 0.01 % hydrogen content.

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