Designation: F1472 – 14

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

This standard is issued under the fixed designation F1472; 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 titanium-6aluminum-4vanadium alloy (UNS R56400) to be used in the manufacture of surgical implants.

1.2 *Units*—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:*[2]

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 X-Ray Fluorescence Spectrometry

E527 Practice for Numbering Metals and Alloys in the Unified Numbering System (UNS)

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

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

2.2 *Aerospace Material Specifications:*[3]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 2631 Ultrasonic Inspection Titanium, and Titanium Alloy Bar, Billet, and Plate

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 6.0 Al 4.0 V Solution Heat Treated and Aged

2.3 *ISO Standards:*[4]

ISO 5832–3 Implants for Surgery—Metallic Materials—Part 3, Wrought Titanium-6Aluminum-4Vanadium Alloy

ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems—Requirements

2.4 *Society of Automotive Engineers Standard:*[3,5]

SAE J1086 Practice for Numbering Metals and Alloys (UNS)

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

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

[3] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

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

[5] New designation established in accordance with Practice E527 and SAE J1086.

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

3.1.3 *stress relieved*—heated to a temperature below the annealing temperature with no observable change in microstructure.

4. Product Classification

4.1 *Strip*—Any product under 4.76 mm [0.1875 in.] in thickness and under 610 mm [24 in.] wide.

4.2 *Sheet*—Any product under 4.76 mm [0.1875 in.] in thickness and 610 mm [24 in.] or more in width.

4.3 *Plate*—Any product 4.76 mm [0.1875 in]. thick and over and 254 mm [10 in.] wide and over, with widths greater than five times thickness. Plate up to 102 mm [4.00 in.] thick, inclusive, is covered by this specification.

4.4 *Bar*—Round bars and flats from 4.76 mm [0.1875 in.] to 150 mm [6.00 in.] in diameter or thickness (other sizes and shapes by special order).

4.5 *Forging Bar*—Bar as described in 4.4, used in the production of forgings. This product may be furnished in the hot worked condition.

4.6 *Wire*—Rounds, flats, or other shapes less than 4.76 mm [0.1875 in.] in diameter or thickness.

4.7 *Billet*—Solid semi-finished section hot worked from an ingot whose intended use is for additional hot or cold reduction

4.8 *Other*—Other forms and shapes, including tubing, may be provided by agreement between purchaser and supplier.

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,

5.1.3 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, abrasively blasted, 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, stress relieved, or cold-worked or hot worked condition. Mechanical properties for conditions other than those listed in Table 3 may be established by agreement between the supplier and the purchaser.

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 verify compliance with this specification.

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 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 E539, E1409, E1447, E1941, E2371, and E2626 or other analytical methods agreed upon between the purchaser and the supplier.

7.3 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 1 Chemical Requirements[A]

Element	Composition, % (mass/mass)
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.

TABLE 2 Product Analysis Tolerance[A]

Element	Tolerance Under the Minimum or Over the Maximum Limit (Composition %)[B] % (mass/mass)
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.002
Iron	0.10
Oxygen	0.02
Aluminum	0.40
Vanadium	0.15
Yttrium	0.0006

[A] See AMS 2249.
[B] Under minimum limit not applicable for elements where only a minimum percentage is indicated.

8. Mechanical Requirements

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

8.2 Specimens for tension tests shall be prepared and tested in accordance with Test Methods E8/E8M or ISO 6892. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 mm/mm/min [in./in./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 over a mandrel with a diameter equal to that shown in Table 3. Test conditions shall conform to Test Method E290.

8.4 *Number of Tests:*

8.4.1 *Bar, Forging Bar, Shapes, and Wire*—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.

8.4.2 Tensile tests results for which any specimen fractures outside the gage length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to Sections 7.11.4 and 7.12.5 of Test Methods E8/E8M. If either the elongation or reduction of area is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements.

8.4.3 *Sheet, Strip, and Plate*—Perform at least one tension test from each lot in the longitudinal direction. Perform at least one bend 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 200 mm [8.0 in.] in length for sheet and 64 mm [2.50 in.] in length for plate can be taken. Should any of these test pieces 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 shall be considered in compliance only if both additional test pieces meet the specified requirements.

9. Special Requirements

9.1 The microstructure shall be a result of processing within the alpha-beta field. Microstructures shall essentially consist of an equiaxed and/or elongated primary alpha in a transformed beta matrix with no continuous network of alpha at prior beta grain boundaries.

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

TABLE 3 Annealed or Annealed and Stress Relieved Mechanical Properties[A]

Size, Nominal Diameter or Distance Between Parallel Sides, mm [in.]	Tensile Strength,[B] MPa, [psi], min	Yield Strength,[B] at 0.2 % Offset, MPa, [psi], min	Elongation[C] in 50 mm [2 in.], or 4D or 4T, %, min			Reduction of Area, %, min[D]		
			L	LT[E]	ST[E,F]	L	LT[E]	ST[E,F]
Bars and Forgings:								
Up to 50 [2.0], incl	930 [135 000]	860 [125 000]	10	...	...	25	...	...
Over 50 to 100 [2.0 to 4.0], incl	895 [130 000]	825 [120 000]	10	10	10	25	20	15
Over 100 to 150 [4.0 to 6.0], incl	895 [130 000]	825 [120 000]	10	10	8	20	15	15
Sheet, Strip, and Plate:								
Up to 0.2 [0.008], excl	924 [134 000]	869 [126 000]	...	...	...	...	...	...
0.2 to 0.6 [0.008 to 0.025], excl	924 [134 000]	869 [126 000]	6	...	...	...	...	...
0.6 to 1.6 [0.025 to 0.063], excl	924 [134 000]	869 [126 000]	8	...	...	...	...	...
1.6 to 4.8 [0.063 to 0.1875], excl	924 [134 000]	869 [126 000]	10	...	...	...	...	...
4.8 to 101.6 [0.1875 to 4.00], incl	895 [130 000]	825 [120 000]	10	10	10	20	20	15
Bending Parameters:								
Up to 1.78 [0.070], incl			bend factor[G] = 9T					
Over 1.78 to 4.75 [0.070 to 0.1875], excl			bend factor[G] = 10T					

[A] Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and the purchaser.
[B] Tensile and yield strength requirements apply in both the longitudinal and transverse directions.
[C] Elongation of material 1.575 mm [0.062 in.] or greater in diameter or thickness shall be measured using a gage length of 50 mm [2 in.] or 4D or 4T. Elongation of material under 1.575 mm [0.062 in.] in diameter or thickness may be obtained by negotiation.
[D] Applies to bar, plate, and forgings only. L = longitudinal; LT = long transverse; ST = short transverse.
[E] Transverse requirements in Table 3 apply only to product from which a tensile specimen not less than 63.5 mm [2.50 in.] in length can be obtained.
[F] Material tested in the short transverse direction need not be tested in the long transverse direction.
[G] Bend test applicable to sheet and strip products: T = thickness of bend specimen in reference to diameter of bend. (Bend factor is the mandrel diameter.)

9.3 Alpha case is not permitted for products supplied with a machined, ground, or chemically milled or pickled surface finish. For other products, there shall be no continuous layer of alpha case ≥0.0254 mm [0.001] in. when examined at 100× magnification.

10. Ultrasonic Inspection

10.1 All centerless ground or peeled and polished round bar ≥9.5mm [0.375 in.] in nominal diameter shall be ultrasonically inspected at final diameter in accordance with AMS 2631, Class A1. Equivalent test methods may be substituted when agreed upon between purchaser and supplier.

11. Significance of Numerical Limits

11.1 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.

12. Certification

12.1 The supplier shall provide a 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.

13. Quality Program Requirements

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

14. Keywords

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

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the chemical, physical, mechanical, and metallurgical properties of wrought annealed titanium-6aluminum-4vanadium alloy to be used in the manufacture of surgical implants.

X1.2 The alloy composition covered by this specification has been used successfully in human implants, exhibiting a well-characterized level of local biological response for over a decade. (**1**, **2**).[6]

X1.3 This alloy exhibits similar mechanical properties to Specification F136 required for the application of load-bearing orthopedic implants (**2-18**).

X1.4 This titanium base alloy, UNS R56400, has been used extensively in the aerospace industry since the 1950's. Aerospace Material Specification AMS 4928 includes the chemical and mechanical properties for Titanium Alloy Bars, Wire, Forgings, Rings, and Drawn Shapes 6Al-4V Annealed. Aerospace Material Specification AMS 4911 includes the chemical and mechanical properties for Titanium Alloy Sheet, Strip, and Plate 6Al-4V Annealed. ISO 5832–3, Implants for surgery–Metallic materials–Part 3: Wrought titanium 6-aluminium4-vanadium alloy also describes titanium base alloy UNS R56400.

X1.5 This alloy can be solution treated and aged to achieve different properties according to, for example, AMS 4965 Titanium Alloy, Bars, Wire, Forgings, and Rings 6.0Al-4.0V Solution Heat Treated and Aged.

[6] The boldface numbers refer to references listed at the end of this standard.

X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this specification has been used successfully in contact with soft tissue and bone for over a decade. (**12**).

X2.2 No known surgical implant material has ever been shown to be completely free from adverse reactions in the human body. Long-term clinical experience of the use of the material referred to in this specification, however, has shown that 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 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 for over a decade. (**1**, **2**, **19**).

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SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F1472 – $08^{\varepsilon 1}$) that may impact the use of this standard. (Approved Nov. 15, 2014.)

(1) Added Test Methods E8/E8M, E539, E1941, E2626, and ISO 6892 to the Referenced Documents section.
(2) Made updates, revisions, and deletions to 6.3, 7.2.4, 8.2, and 9.1.
(3) Added new Section 10.
(4) Added other corrections and changes to better correspond to Specification F136.
(5) Revised standard to make SI units primary