



# Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)<sup>1</sup>

This standard is issued under the fixed designation F 1472; 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 ( $\epsilon$ ) 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 The values stated in inch-pound units are to be regarded as the standard. The SI equivalents in parentheses are provided for information only.

## 2. Referenced Documents

### 2.1 ASTM Standards:

E 8 Test Methods of Tension Testing of Metallic Materials<sup>2</sup>

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys<sup>3</sup>

E 290 Test Method for Bend Testing of Materials for Ductility<sup>2</sup>

E 527 Practice for Numbering Metals and Alloys (UNS)<sup>4</sup>

E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique<sup>3</sup>

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method<sup>5</sup>

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone<sup>6</sup>

### 2.2 ASQ Standard:

C1 Specifications of General Requirements for a Quality Program<sup>7</sup>

### 2.3 Aerospace Material Specifications:<sup>8</sup>

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:

SAE J1086 Practice for Numbering Metals and Alloys (UNS)<sup>9</sup>

## 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 in. (4.75 mm) in thickness and under 24 in. (610 mm) wide.

4.2 *Sheet*—Any product under 0.1875 in. (4.75 mm) in thickness and 24 in. (610 mm) or more in width.

4.3 *Plate*—Any product 0.1875 in. (4.75 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 mm) thick, inclusive, is covered by this specification.

4.4 *Bar*—Round bars and flats from 0.1875 in. (4.75 mm) to 4.00 in. (101.60 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.

4.6 *Wire*—Rounds or flats less than 0.1875 in. (4.75 mm) in diameter.

## 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,

<sup>1</sup> 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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<sup>2</sup> *Annual Book of ASTM Standards*, Vol 03.01.

<sup>3</sup> *Annual Book of ASTM Standards*, Vol 03.05.

<sup>4</sup> *Annual Book of ASTM Standards*, Vol 01.01.

<sup>5</sup> *Annual Book of ASTM Standards*, Vol 03.06.

<sup>6</sup> *Annual Book of ASTM Standards*, Vol 13.01.

<sup>7</sup> Available from American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

<sup>8</sup> Available from SAE, 400 Commonwealth Dr., Warrendale, PA 15096-0001.

<sup>9</sup> New designation established in accordance with E 527 and SAE J1086.

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

- 5.1.3 Form (sheet, strip, plate, 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, 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.

6.3 *Condition*—Material shall be furnished in the annealed or cold-worked condition.

## 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 Table 2.

7.2.1 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.

**TABLE 1 Chemical Requirements<sup>A</sup>**

Element	Composition, %
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max <sup>B</sup>	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 <sup>C</sup>	balance

<sup>A</sup> Refer to AMS 4928.

<sup>B</sup> Billets shall have a maximum of 0.01 % hydrogen content.

<sup>C</sup> The percentage of titanium is determined by difference and need not be determined or certified.

**TABLE 2 Product Analysis Tolerance<sup>A</sup>**

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

<sup>A</sup> See AMS 2249.

<sup>B</sup> Under minimum limit not applicable for elements where only a minimum percentage is indicated.

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

7.2.3 For referee purposes, use Test Methods E 120, E 1409, and E 1447 or other analytical methods agreed upon between the purchaser and the supplier.

7.3 Ensure that the samples for chemical analysis are 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.

8.2 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 a mandrel that has 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 *Sheet, Strip, and Plate*—Perform at least one tension and one bend test from each lot. Tension and bend property requirements apply 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 sheet and 2.50 in. (64 mm) in length for plate can be taken. Should any of these test specimens not meet the

**TABLE 3 Annealed Mechanical Properties<sup>A</sup>**

Size, Nominal Diameter or Distance Between Parallel Sides, in. (mm)	Tensile Strength, <sup>B</sup> psi, (MPa), min	Yield Strength, <sup>B</sup> at 0.2 % Offset, psi (MPa), min	Elongation <sup>C</sup> in 2 in. (50 mm), or 4D or 4T, %, min			Reduction of Area, %, min <sup>D</sup>		
			L	LT <sup>E</sup>	ST <sup>E,F</sup>	L	LT <sup>E</sup>	ST <sup>E,F</sup>
<i>Bars and Forgings:</i>								
Up to 2.0 (50), incl	135 000 (930)	125 000 (860)	10	...	...	25	...	...
Over 2.0 to 4.0 (50 to 100), incl	130 000 (895)	120 000 (825)	10	10	10	25	20	15
Over 4.0 to 6.0 (100 to 150), incl	130 000 (895)	120 000 (825)	10	10	8	20	15	15
<i>Sheet, Strip, and Plate:</i>								
Up to 0.008 (0.2), excl	134 000 (924)	126 000 (869)	...	...	...	...	...	...
0.008 to 0.025 (0.2 to 0.6), excl	134 000 (924)	126 000 (869)	6	...	...	...	...	...
0.025 to 0.063 (0.6 to 1.6), excl	134 000 (924)	126 000 (869)	8	...	...	...	...	...
0.063 to 0.1875 (1.6 to 4.8), excl	134 000 (924)	126 000 (869)	10	...	...	...	...	...
0.1875 to 4.00 (4.8 to 101.6), incl	130 000 (895)	120 000 (825)	10	10	10	20	20	15
<i>Bending Parameters:</i>								
Up to 0.07 (1.875), incl						bend factor <sup>G</sup> = 9T		
Over 0.07 to 0.1875 (4.8), excl						bend factor <sup>G</sup> = 10T		

<sup>A</sup> Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and the purchaser.

<sup>B</sup> Tensile and yield strength requirements apply in both the longitudinal and transverse directions.

<sup>C</sup> Elongation of material 0.062 in. (1.575 mm) or greater in diameter or thickness shall be measured using a gage length of 2 in. or 4D or 4T. Elongation of material under 0.062 in. in diameter or thickness may be obtained by negotiation.

<sup>D</sup> Applies to bar, plate, and forgings only. L = longitudinal; LT = long transverse; ST = short transverse.

<sup>E</sup> Transverse requirements in Table 3 apply only to product from which a tensile specimen not less than 2.50 in. (63.5 mm) in length can be obtained.

<sup>F</sup> Material tested in the short transverse direction need not be tested in the long transverse direction.

<sup>G</sup> 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.)

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.

## 9. Special Requirements

9.1 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.

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.

9.3 Alpha case is not permitted for products supplied with a machined, ground, or chemically milled surface finish. For

other products, there will be no continuous layer of alpha case when examined at 100× magnification.

## 10. Certification

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

## 11. Quality Program Requirements

11.1 The producer shall maintain a quality program as defined in ASQ C1.

## 12. Keywords

12.1 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 since 1983. **(1, 2)**.<sup>10</sup>

X1.3 This alloy exhibits similar mechanical properties to Specification F 136 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 standard 5832-3, Implants for

<sup>10</sup> The boldface numbers refer to references listed at the end of this standard.

surgery—Metallic materials—Part 3: Wrought titanium 6-aluminum-4-vanadium alloy also describes titanium base alloy UNS R56400.

different properties according to, for example, AMS 4965 Titanium Alloy, Bars, Wire, Forgings, and Rings 6.0Al-4.0V Solution Heat Treated and Aged.

X1.5 This alloy can be solution treated and aged to achieve

## X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this specification has been used successfully in contact with soft tissue and bone since 1983 (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 since 1983 (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 (F 1472 – 02) that may impact the use of this standard.

- (1) Section 3, Terminology, was added.
- (2) Section 8.4 was revised, and subsections 8.4.1 and 8.4.2 were added.

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