Designation: F 1472 – 99

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

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 (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) standard grade titanium alloy 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 metric equivalents in parentheses are provided for information only.

2. Referenced Documents

2.1 *ASTM Standards:*

F 136 Specification for Wrought Titanium 6Sl-4V ELl Alloy for Surgical Implant Applications[2]

B 265 Specification for Titanium and Titanium Alloy Strip, Sheet and Plate[3]

B 348 Specification for Titanium and Titanium Alloy Billets[3]

B 381 Specification for Titanium and Titanium Alloy Forgings[3]

E 8 Test Methods of Tension Testing of Metallic Materials[4]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[5]

E 290 Test Method for Semi-Guided Bend Test for Ductility of Metallic Materials[4]

E 527 Practice for Numbering Metals and Alloys (UNS)[6]

E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique[5]

E 1447 Test Method for Determination of Hydrogen in Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method[7]

2.2 *Other Standards:*

ASQC C1 Specifications of General Requirements for a Quality Control Program[8]

2.3 *Aerospace Material Specifications:*

AMS 4928L Titanium Alloy Bars, Forgings and Rings 6Al-4V[9]

AMS 2249C Chemical Check Analysis Limits, Titanium and Titanium Alloys[9]

2.4 *Society of Automotive Engineers Standard:*

SAE J1086 Practice for Numbering Metals and Alloys (UNS)[9]

3. Product Classification

3.1 *strip*—any product under 0.1875 in. (4.76 mm in thickness and under 24 in. (610 mm) wide.

3.2 *sheet*—any product under 0.1875 in. (4.76 mm) in thickness and 24 in. (610 mm) or more in width.

3.3 *plate*—any product 0.1875 in. (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 mm), thick inclusive is covered by this specification.

3.4 *bar*—rounds from 0.1875 in. (7.9 mm) to 4.00 in. (101.60 mm) in diameter. (Other sizes by special order.)

3.5 *forging bar*— bar as described in 3.4, used for production of forgings, may be furnished in the hot rolled condition.

3.6 *wire*—rounds less than 0.1875 in. (4.76 mm) in diameter.

4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:

4.1.1 Quantiy (weight or number of pieces),

4.1.2 Applicable ASTM designation,

4.1.3 Form (sheet, strip, plate, wire, bar, or forging),

4.1.4 Condition (see 5.1),

4.1.5 Mechanical properties (if applicable, for special conditions),

4.1.6 Finish (see 5.2),

4.1.7 Applicable dimensions including size, thickness, width, or print number,

4.1.8 Special tests, and

4.1.9 Special requirements

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

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[2] *Annual Book of ASTM Standards*, Vol 13.01.

[3] *Annual Book of ASTM Standards*, Vol 02.04.

[4] *Annual Book of ASTM Standards*, Vol 0301.

[5] *Annual Book of ASTM Standards*, Vol 03.05.

[6] *Annual Book of ASTM Standards*, Vol 01.01.

[7] *Annual Book of ASTM Standards*, Vol 03.06.

[8] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

[9] Available from the Society of Automotive Engineers, 3001 W. Big Beaver, Troy, MI 48084.

5. Materials and Manufacture

5.1 The various titanium mill products covered in this specification are normally formed with the conventional forging and rolling equipment found in primary ferrous and non-ferrous plants. The ingot metal for such mill operations is usually melted in non consumable, plasma, EB or arc furnaces of a type conventionally used for reactive metals.

5.2 *Finish*—Annealed material may be furnished to the implant manufacturer as descaled or pickled, sandblasted, ground, machined, vapor-blasted, or combinations of these operations.

5.3 Alloy shall be multiple melted; at least one of the melting cycles shall be under vacuum. The first melt shall be made by consumable electrode, nonconsumable electrode, electron beam, or plasma arc melting practice. The subsequent melt or melts shall be made using consumable electrode practice with no alloy additions permitted in the last consumable electrode melt.

5.3.1 The atmosphere for nonconsumable electrode melting shall be inert gas at a pressure not higher than 250 mm of mercury.

5.3.2 The electrode tip for nonconsumable electrode melting shall be water-cooled copper.

5.3.3 The product, as received by the purchaser, shall be uniform in quality and condition, sound, and free from foreign materials and from internal and external imperfections detrimental to usage of the product.

6. Chemical Requirements

6.1 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.

6.2 The product analysis tolerances shall conform to the check tolerances of Table 2.

6.3 For referee purposes, Test Methods E 120, E 1409,and E 1447 shall be used.

6.4 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. Therefore, in cutting samples for analysis, the operation should be carried out insofar as possible in a dust-free atmosphere. Chips should be clean and sharp. Samples for analysis should be stored in suitable containers. Cutting tools should be clean and sharp. Chips should be clean.

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.

TABLE 2 Permissible Variation in Product Analysis Tolerance[A]

Element	Variation Under Min or Over Max
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.002
Iron	0.10
Oxygen	0.02
Aluminum	0.04
Vanadium	0.015
Yttrium	0.0006

[A] Refer to AMS 2249.

7. Mechanical Requirements

7.1 Material supplied under this specification shall conform to the mechanical property requirements given in Table 3.

7.2 Specimens for tension tests shall be machined and tested in accordance with Test Method E 8. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in. min (metric equivalent mm/mm min) through the specified yield strength, and then the crosshead speed shall be increased so as to produce fracture in approximately one additional minute.

7.3 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 on a diameter equal to that shown in Table 3. Test condition shall conform to Test Method E 290.

8. Special Requirements

8.1 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.

8.2 The beta transus temperature shall be measured by a suitable method and reported on the materials certification.

8.3 Products supplied with a machined or ground surface finish shall have no alpha case. For other products, there shall be no continous layer of alpha case when examined at 100x.

9. Quality Program Requirements

9.1 The producer shall maintain a quality program that is defined in Specification ANSI/ASQC C1.

9.2 The manufacturer of surgical implants or medical appliances shall be assured of and may audit the producer's quality program for conformance to the intent of Specification ANSI/ASQC C1-1985, or other recognized program.

10. Marking, Packing, Certification, and Rejection

10.1 Marking, packing, certification, and rejection shall be as specified in Specifications B 265, B 348, and B 381.

11. Keywords

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

TABLE 3 Annealed Mechanical Properties[A]

Nominal Diameter or Distance Between Parallel Sides, Inches (mm)	Tensile Strength psi, min (MPa)	Yield Strength at 0.2 % Offset psi, min (MPa)	Elongation[B] in 2 in. or 4D, %, min			Reduction of Area %, min		
			Long.	L.T.[C]	S.T.[C]	Long.	L.T.[C]	S.T.[C]
Bars and Forgings								
Up to 2.0, incl. (50)	135 000 (930)	125 000 (860)	10			25	20	
Over 2.0 to 4.0, incl. (50 to 100)	130 000 (895)	120 000 (825)	10			25	20	15
Over 4.0 to 6.0, incl. (100 to 150)	130 000 (895)	120 000 (825)	10		8	20	15	
Sheet Strip and Plate								
Up to 0.008, excl. (0.2)	134 000 (924)	126 000 (869)						
0.008 to 0.025, excl. (0.2 to 0.6)	134 000 (924)	126 000 (869)	6					
0.025 to 0.063, excl. (0.6 to 1.6)	134 000 (924)	126 000 (869)	8					
0.063 to 0.1875, excl. (1.6 to 4.8)	134 000 (924)	126 000 (869)	10					
0.1875 to 4.00, incl. (4.8 to 101.6)	130 000 (895)	120 000 (825)	10					
Up to 0.07, incl. (1.78)			Bend Factor = 9T					
Over 0.07 to 0.1875, excl. (4.8)			Bend Factor = 10T					

[A]Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and the implant manufacturer.
[B]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 4W. Elongation of material under 0.062 in. (1.575 mm) in diameter or thickness may be obtained by negotiation. L = longitudinal; LT = long traverse; ST = short transverse.
[C]Applies to bar, plate, and forgings only. L = longitudinal; LT = long transverse; ST = short transverse.

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 Ti-6Al-4V alloy to be used in the manufacture of surgical implants.

X1.2 The alloy composition covered by this standard has been employed successfully in human implants, exhibiting a well-characterized level of local biological response since 1983.**(1, 2)**.[10]

X1.3 The microstructural requirements contained in this standard represent the current general consensus of opinion with respect to optimization of mechanical properties for implant applications.

X1.4 This alloy exhibits similar mechanical properties to Specification F 136 required for the application of load-bearing orthopedic implants **(2-18)**.

X1.5 Melting requirements specified in AMS 4928L have been included to ensure that melting practice conforms to industry guidelines for standard grade titanium - 6aluminum - 4vanadium.

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

X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this standard has been employed successfully in contact with soft tissue and bone since 1983 (**12**)

X2.2 No known surgical implant has ever 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 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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