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Standard Specification for Wrought Titanium-13Niobium-13Zirconium Alloy for Surgical Implant Applications (UNS R58130)¹

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1. Scope

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought titanium-13niobium-13zirconium alloy to be used in the manufacture of surgical implants (1).²

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:³
- E8 Test Methods for Tension Testing of Metallic MaterialsE29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
- 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

- 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 - E2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry (Withdrawn 2013)⁴
 - F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)

- 2.2 Aerospace Material Specification:
- AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys⁵
- 2.3 American Society for Quality (ASQ) Standard:
- ASQ C1 Specifications of General Requirements for a Quality Program⁶
- 2.4 ISO Standards:
- ISO 5832-3 Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy⁷
- ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature⁷

ISO 9001 Quality Management Systems—Requirements⁷

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 *capability-aged*, *adj*—the condition of the material that is obtained if, following solution treatment, a sample of the mill product is subjected to an aging treatment such as given below, for certification testing.

3.1.2.1 Age for 6 \pm 0.25 h at 923 \pm 25°F (495 \pm 14°C).

3.1.2.2 Remove from furnace and air cool to room temperature.

3.1.3 *cold work, n*—any mechanical deformation process performed below the recrystallization temperature which results in strain hardening of the material.

3.1.4 *hot work, n*—any mechanical deformation process performed above the recrystallization temperature.

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

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 $^{^{2}}$ The boldface numbers in parentheses refer to the list of references at the end of this standard.

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.

 $^{^{\}rm 4}\,{\rm The}$ last approved version of this historical standard is referenced on www.astm.org.

⁵ Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

⁶ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

⁷ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.6 solution-treated, adj—the condition of the material that is obtained if, following the final hot-working or cold-working operation, the mill product is rapidly quenched, for example, by water quenching, from a temperature above 1112°F (600°C).

3.1.7 *unannealed*, *adj*—the condition of the material that is obtained after the normal hot-working or cold-working operation used for fabrication of the mill product. There are no subsequent heat treatment requirements.

4. Product Classification

4.1 *Bar*—Rounds or flats from 0.188 in. (4.76 mm) to 4 in. (101.6 mm), inclusive, in diameter or thickness. (Other sizes and shapes by special order.)

4.2 *Wire*—Rounds or flats 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 (weight or number of pieces);

5.1.2 Applicable ASTM designation and year of issue;

5.1.3 Form (wire or bar, see Section 4);

5.1.4 Condition (see 6.2);

5.1.5 Mechanical properties (if applicable, for special conditions) (see 8.1);

5.1.6 Finish (see 6.1);

5.1.7 Applicable dimensions including size, diameter, thickness (for rectangular wire), or print number;

5.1.8 Special tests (if any); and

5.1.9 Other requirements.

6. Materials and Manufacture

6.1 *Finish*—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. On bars, it is permissible to remove minor surface imperfections by grinding if the resultant area meets the dimensional and surface finish requirements of this specification.

6.2 *Condition*—Material shall be furnished in the unannealed, solution-treated, or capability-aged condition, as specified in the purchase order. Conditions and mechanical properties 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.

TABLE	1	Chemical	Requirements
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Element	Composition (% mass/mass)	
Nitrogen, max	0.05	
Carbon, max	0.08	
Hydrogen, max	0.012 ^A	
Iron, max	0.25	
Oxygen, max	0.15	
Niobium	12.5–14.0	
Zirconium	12.5–14.0	
Titanium ^B	balance	

 $^{\it A}$ Material 0.032 in. (0.813 mm) and under may have hydrogen content up to 0.015 %.

 $^{\ensuremath{B}}$ The percentage of titanium is determined by difference and need not be determined or certified.

TABLE 2 Product Analysis Tolerance	, A
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Element		Tolerance Under the Minimum		
		or Over the Maximum Limit (% mass/mass) ⁸		
Nitrogen Carbon Hydrogen Iron Oxygen Niobium		0.02 0.02 0.0020 0.10 0.02 0.30		
Zirconium		0.40		

^A Refer to AMS 2249.

^B Under the minimum limit not applicable for elements where only a maximum percentage is indicated.

TABLE 3 Mechanical Properties^{A,B}

Preview Condition	Tensile Strength min, psi (MPa)	Yield Strength (0.2 % offset), min psi (MPa)	Elongation min, % ^C	Reduction of Area min, % ^D
Capability aged	125 000	105 000	8	15
	- (860) C24	(725) Str		
Solution treated	80 000	50 000	15	30
	(550)	(345)		
Unannealed	80 000	50 000	8	15
	(550)	(345)		

^A Up to 4 in. (101.60 mm) inclusive diameter.

^{*B*} Solution treated or unannealed material is not intended for use as a final product without subsequent hot working or heat treatment, or both.

 $^{\rm C}$ Limits apply to tests taken both longitudinal and transverse to the direction of rolling. Elongation of material 0.063 in. (1.575 mm) or greater in diameter (D) or thickness (T) shall be measured using a gage length of 2 in. or 4D or 4T. The gage length shall be reported with the test results. The method for determining elongation of material under 0.063 in. (1.575 mm) in diameter or thickness may be negotiated. Alternately, a gage length corresponding to ISO 6892 may be used when agreed upon between the supplier and purchaser. (5.65 square root $S_{\rm o}$, where $S_{\rm o}$ is the original cross sectional area.)

^D Applies to bar only.

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 to determine variations in the composition within the heat.