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Standard Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications [UNS R56700][1]

This standard is issued under the fixed designation F 1295; 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-6 aluminum-7 niobium alloy bar to be used in the manufacture of surgical implants **(1-4)**.[2]

1.2 The values stated in inch-pound units are to be regarded as the standard. The SI (metric) units given in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards:*

E 8 Test Methods for Tension Testing of Metallic Materials[3]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[4]

E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Insert Gas Fusion Technique[4]

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Insert Gas Fusion Thermal Conductivity Method[5]

F 981 Practice for Assessment of Compatibility of Biiomaterials for Surgical Implants with Respect to Effect of Materials in Muscle and Bone[6]

2.2 *Aerospace Material Specification:*

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys[7]

2.3 *ASQC Standard:*

C1 Specification of General Requirements for a Quality Program[8]

3. Ordering Information

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

3.1.1 Quantity (weight or number of pieces),

3.1.2 ASTM designation,

3.1.3 Dimensions,

3.1.4 Condition,

3.1.5 Finish, and

3.1.6 Special requirements.

4. Materials and Manufacture

4.1 The titanium alloy shall be manufactured from multiple vacuum melted material using conventional reactive metal processing methods. The bar product covered in this specification is normally formed with the conventional forging and rolling equipment found in ferrous and nonferrous plants.

4.2 *Finish*—Annealed bar may be furnished to the implant manufacturer as descaled or pickled, sandblasted, ground, or combinations of these operations.

5. Chemical Composition

5.1 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.

5.1.1 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 certify compliance with this specification.

5.2 *Product Analysis*:

5.2.1 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. The manufacturer shall not ship material that is outside the limits specified in Table 1. Product analysis limits shall be as specified in Table 2.

5.2.2 The product analysis is either for the purpose of verifying the composition of a heat or lot or to determine variations in the composition within the heat.

5.3 For referee purposes, Test Methods E 120, E 1409, and E 1447 shall be used or other analytical methods agreed upon between purchaser and supplier shall be used.

5.4 Samples for chemical analysis shall be representative of

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[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devicesand is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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[2] The boldface numbers in parentheses refer to a list of references at the end of the text.

[3] *Annual Book of ASTM Standards*, Vols 01.02, 02.01, 02.02, 02.03, and 03.01.

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

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

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

[7] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.

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

TABLE 1 Chemical Requirements

Element	Composition, %
Aluminum	5.50 to 6.50
Niobium	6.50 to 7.50
Tantalum	0.50 max
Iron	0.25 max
Oxygen	0.20 max
Carbon	0.08 max
Nitrogen	0.05 max
Hydrogen	0.009 max
Titanium[A]	Balance

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

TABLE 2 Product Analysis Tolerances[A]

Tolerance Under the Minimum[B] or Over the Maximum Limit	
Aluminum	0.10
Niobium	0.10
Tantalum	0.10
Iron	0.10
Oxygen	0.02
Carbon	0.02
Nitrogen	0.02
Hydrogen	0.002

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

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 any contamination should be avoided. Chips should be clean and sharp cutting tools should be used. Samples for analysis should be stored in suitable containers.

6. Mechanical Properties

6.1 Material supplied under this specification shall conform to the mechanical properties given in Table 3.

6.2 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. through the specified yield strength and then the crosshead speed shall be increased so as to produce fracture in approximately one additional minute.

TABLE 3 Annealed Mechanical Properties for Bar[A]

Ultimate Tensile Strength, min, psi, (MPa)	Yield Strength (0.2 % offset), min, psi, (MPa)	Elongation,[B] min, %	Reduction of area, min, %
130 500 (900)	116 000 (800)	10	25

[A] Up to 3.94 in. (100 mm) diameter or thickness.
[B] Gage length = 5.65 $\sqrt{S_o}$ or 2 in. (50 mm), where S_o is the original cross-sectional area.

6.3 *Number of Tests*— A minimum of two tension tests shall be made from each lot. A lot is defined as the total number of a specific mill product produced under the same conditions at essentially the same time. Should either of the test specimens not meet the specific requirements or break outside the gage limits, two additional test pieces representative of the same lot shall be tested in the same manner. The lot shall be rejected if either of the additional test pieces fail to meet the specified requirements.

7. Microstructure

7.1 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. There shall be no alpha case.

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

7.3 A minimum of one sample per lot shall be examined.

8. Certification

8.1 A certificate of tests shall be provided with the following information:

8.1.1 Heat number,

8.1.2 Mill or purchase number, or both,

8.1.3 Chemical analysis including Al, Nb, Ta, Fe, O, C, N, and H,

8.1.4 Mechanical properties (tensile strength, yield strength, elongation, reduction of area),

8.1.5 Surface finish,

8.1.6 Quantity delivered,

8.1.7 Date of shipment,

8.1.8 Size and condition, and

8.1.9 Specification.

9. Product Marking

9.1 The name of the manufacturer, heat number, lot number, specification number, and year of issue shall be legibly and durably marked.

10. Quality Assurance

10.1 The producer shall maintain a quality assurance program, for example, such as defined in ASQC C1.

10.2 The manufacturer of surgical implants shall be assured of the producer's quality assurance program for conformance to the intent of ASQC C1 or other recognized program.

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the composition and properties of wrought annealed Ti-6A1-7Nb titanium alloy bar to ensure consistency in the starting material used in the manufacture of medical devices, in particular of surgical implants.

X1.2 The microstructural requirements contained in this specification represent the current general consensus of opinion with respect to optimization of mechanical properties for implant applications.

X1.3 The minimum mechanical properties specified ensure a baseline of strength and ductility for the highly stressed devices that may be manufactured from this alloy.

X1.4 The stress corrosion cracking resistance of this alloy is similar to Ti-6A1-4V alloy.

X1.5 The UNS designation has been added, residual element language has been included, alpha case information has been clarified, the inclusion requirement has been deleted because no standard method exists for determining the inclusion content in titanium alloys, and Appendix X2 Biocompatibility section has been added to the Rationale.

X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this standard has been employed successfully in contact with soft tissue and bone for over a decade.

X2.2 No known surgical implant has ever been 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 **(5)** 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 1986 **(6 and 7)**.

REFERENCES

(**1**) Semlitsch, M., Straub, F., and Weber, H., "Titanium-Aluminium-Niobium Alloy, Development of Biocompatible, High Strength Surgical Implants," *Biomedizinische Technik 30*, 12, 1985, pp. 334–339.

(**2**) Maeusli, P. A., Block, P. R., Geret, V., and Steinemann, S. G., "Surface Characterization of Titanium and Titanium Alloys," *Biological and Biomechanical Performance of Biomaterials*, edited by Christel, Meunier, and Lee, Elsevier Science Publ., 1986, pp. 57–62.

(**3**) Simpson, J. P., "The Electrochemical Behaviour of Titanium and Titanium Alloys with Respect to their Use as Surgical Implant Materials," *Biological and Biomechanical Performance of Biomaterials*, 1986, pp. 63–68.

(**4**) Semlitsch, M., Staub, F., and Weber, H., "Development of a Vital, High-Strength Titanium-Aluminium-Niobium Alloy for Surgical Implant Materials," *Biological and Biomechanical Performance of Biomaterials*, 1986, pp. 69–74.

(**5**) Perren, S. M., Geret, V., Tepic, M., and Rahn, B. A., "Quantitative Evaluation of Biocompatibility of Vanadium-Free Titanium Alloys," *Biological and Biomechanical Performance of Biomaterials*, 1986, pp. 397–402.

(**6**) Semlitsch, M.," Titanium Alloys for Hip Joint Replacements," *Clinical Materials*, 2, 1987, pp. 1–13.

(**7**) Zweymüller, K. A., Lintner, F. K., and Semlitsch, M. F., "Biologic Fixation of a Press-Fit Titanium Hip Joint Endoprosthesis," *Clinical Orthopaedics and Related Research* 235, Oct. 1988, pp. 195–206.