Designation: F 1295 – ~~97a~~01

Standard Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications ~~[UNS R56700]~~[1] (UNS R567000)

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

~~[1] This specification is under the jurisdiction~~

[1] The boldface numbers in parentheses refer to a list of ~~ASTM Committee F-4 on Medical and Surgical Materials and Devices and is~~ references at the ~~direct responsibility~~ end of ~~Subcommittee F04.12 on Metallurgical Materials.~~

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

aluminum-7 niobium alloy bar and wire to be used in the manufacture of surgical implants **(1-4)**.[1]

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

2. Referenced Documents

2.1 *ASTM Standards:*

E 8 Test Methods for Tension Testing of Metallic Materials[2]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[3]

E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Insert Gas Fusion Technique[3]

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Insert Gas Fusion Thermal Conductivity Method[4]

F 981 Practice for Assessment of Compatibility of Biiomaterials for Surgical Implants with Respect to Effect of Materials in Muscle and Bone[5]

2.2 *ISO Standards:*

ISO 5832–11 Implants for Surgery—Metallic Materials—Part 11: Wrought Titanium 6–Aluminum 7–Niobium Alloy[6]

ISO 6892 Metallic Materials—Tensile Testing[6]

2.3 *Aerospace Material Specification:*

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

2.~~3~~4 *American Society for Q~~C~~uality Standard:*

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

3. ~~Ordering Information~~

~~3.1 Inquiries~~Product Classification

3.1 Bar—Rounds or flats from 0.1875 in. (4.76 mm) to 4 in. (101.60 mm) in diameter or thickness. Other sizes and shapes by special order.

3.2 Forging Bar—Bar as described in 3.1, used for ~~material under this specification shall include~~ the ~~following information:~~

~~3.1.1 Quantity (weight or number~~ production 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.~~ forgings, may be furnished in the hot rolled condition.

3.3 Wire—Rounds or flats less than 0.1875 in. (4.76 mm) in diameter or thickness.

4. Ordering Information

4.1 Include with inquiries and orders for material under this specification the following information:

4.1.1 Quantity (weight or number of pieces),

4.1.2 Applicable ASTM designation, date of issue.

4.1.3 Form (bar or wire),

4.1.4 Condition (see 5.3),

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 drawing number,

4.1.8 Special tests, if any,

4.1.9 Other requirements.

5. Materials and Manufacture

~~4~~5.1 The various titanium ~~alloy shall be manufactured from multiple vacuum melted material using conventional reactive metal processing methods. The bar product~~ mill products covered in this specification ~~is~~ normally are formed with the conventional

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~~[1] The boldface numbers in parentheses refer to a list~~

[2] *Annual Book of ~~references at the end of the text.~~ ASTM Standards*, Vols 01.02, 02.01, 02.02, 02.03, and 03.01.

[3] *Annual Book of ASTM Standards*, ~~Vols 01.02, 02.01, 02.02, 02.03, and 03.01.~~ Vol 03.05.

[4] *Annual Book of ASTM Standards*, Vol 03.0~~5~~6.

[5] *Annual Book of ASTM Standards*, Vol ~~03.06.~~ 13.01.

~~*Annual Book of ASTM*~~

[6] Available from American National Standards~~, Vol 13.01.~~ Institute, 25 W. 43rd St., 4th Floor, New York, NY, 10036.

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

[8] Available from American Society for ~~Quality Control, 161 West Wisconsin~~ Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

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.

45.2 *Finish*—Annealed bar—The mill product may be furnished to the implant manufacturer as descaled or pickled, sandblasted, chemically milled, ground, machined, peeled, polished, or combinations of these operations.

5. as specified by the purchaser.

5.3 *Condition*—Material shall be furnished in the annealed or hot rolled condition.

6. Chemical Composition

5.1 The 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. The supplier shall not ship material outside the limits specified in Table 1.

56.1.1 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.

56.2 *Product Analysis*:

56.2.1 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. P The product analysis limits tolerances shall be as specified in conform to Table 2.

56.2.2 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.

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

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

5.4 Samples the supplier.

6.4 Ensure that the samples for chemical analysis shall be 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. Therefore, in In cutting samples for analysis any contamination analysis, therefore, the operation should be avoided. Chips carried out insofar as possible in a dust-free atmosphere. Cutting tools should be clean and sharp cutting tools should be used. sharp. Samples for analysis should be stored in suitable containers.

67. Mechanical Properties

6.1 Material Requirements

7.1 The material supplied under this specification shall conform to the mechanical properties given in Table 3.

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

67.3 *Number of Tests*— A—Perform 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 two test specimens not meet the specific requirements or break outside the gage limits, specified requirements, test two additional test pieces representative of the same lot shall be tested in the same manner. The lot shall will be rejected in compliance only if either of the both additional test pieces fail to meet the specified requirements.

7. Microstructure

7.1 The microstructure shall be requirements. If a fine dispersion of specimen fails outside the alpha and beta phases resulting from processing in gage, the alpha plus beta field. There shall be no continuous alpha network at prior beta grain boundaries. There

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.

TABLE 3 Annealed Mechanical Properties for Bar[A] Mechanical Properties for Bar and Wire[B]

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

[A] Mechanical properties for the hot rolled condition (100 mm) may be established by agreement between the supplier and purchaser.
[B] Gage length for 4.00-in. (101.60-mm), diameter or thickness.
[C] Elongation of material 0.062 in. (1.575 mm) or greater in diameter or thickness shall be measured using a gage length of 4D or 4W or 5.65 $\sqrt{So}$, where So is the original cross-sectional area. The gage length must be reported with the test results. The method for determining elongation of material under 0.062 in. (1.57 mm) in diameter or thickness may be negotiated. Alternately, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser.

shall be no coarse, elongated alpha platelets. There shall be no alpha case.

7.2 Products supplied test is null in accordance with Test Methods E 8, and a machined or ground surface finish retest 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. performed.

8. Certification

8.1 A certificate 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 provided with no continuous alpha network at prior beta grain boundaries. There shall be no coarse, elongated alpha platelets.

8.2 Determine 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, beta transus temperature for each heat by a suitable method and H,

8.1.4 Mechanical properties (tensile strength, yield strength, elongation, reduction report on the material certification if required by the purchaser.

8.3 Alpha case is not permitted for products supplied with a machined, ground, or chemically milled surface finish. For other products, there shall be no continuous layer 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. alpha case when examined at 100 X magnification.

9. Product Marking Certification

9.1 The name of supplier's certification that the manufacturer, heat number, lot number, material was manufactured in accordance with this specification number, and year together with a report of issue the test results shall be legibly and durably marked. furnished to the implant manufacturer at the time of shipment.

10. Quality Assurance Program Requirements

10.1 The producer shall maintain a quality assurance program, for example, such program 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.

11. Keywords

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

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.

X1.6 ISO standards are listed for reference only. Use of the ISO standards in addition to or instead of the preferred ASTM standard may be negotiated between the purchaser and supplier.

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~~(6, 7)**.

REFERENCES

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(**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.

SUMMARY OF CHANGES

(*1*) Flats and other shapes have been added to 3.1, forging bar has been added to 3.2, and wire has been added to 3.3 to reflect current product forms.
(*2*) Editorial corrections have been made to meet terminology and formatting guidelines established for implant material standards.