Designation: F 1713 – 03

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

This standard is issued under the fixed designation F 1713; 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 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 the standard. The SI equivalents in parentheses are provided for information only.

2. Referenced Documents

2.1 *ASTM Standards:*

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

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

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[5]

F 1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)[5]

2.2 *Aerospace Material Specification:*

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys[6]

2.3 *American Society for Quality (ASQ) Standard:*

ASQ C1 Specifications of General Requirements for a Quality Program[7]

2.4 *ISO Standard:*

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature[8]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *capability aged, n*—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.

3.1.1.1 Age for 6 ± 0.25 h at 923 ± 25°F (495 ± 14°C).

3.1.1.2 Remove from furnace and air cool to room temperature.

3.1.2 *solution treated, n*—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).

3.1.3 *unannealed, n*—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 3⁄16 in. (4.75 mm) to 4 in. (101.60 mm), inclusive, in diameter or thickness. (Other sizes and shapes by special order.)

4.2 *Wire*—Rounds or flats less than 3⁄16 in. (75 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,

5.1.3 Form (wire or bar),

5.1.4 Condition (see Section 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, diameter, thickness (for rectangular wire), or print number,

5.1.8 Special tests, and

5.1.9 Special requirements.

[1] 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.

Current edition approved June 10, 2003. Published July 2003. Originally approved in 1996. Last previous edition approved in 1996 as F 1713 – 96.

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

[3] *Annual Book of ASTM Standards*, Vol 03.01.

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

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

[6] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001.

[7] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

[8] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

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

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 implant manufacturer as descaled, pickled, sandblasted, ground, machined, or combinations of these operations.

7. Chemical Requirements

7.1 Ensure that the heat analysis conforms to the chemical composition of Table 1. Ingot analysis may be used for reporting all chemical requirements, except hydrogen. Take samples for hydrogen from the finished mill product.

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 tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the overcheck measurement of chemical content. The manufacturer shall not ship material that is outside the limits specified in Table 1. Overcheck analyses outside the Product Analysis Tolerances of Table 2 are cause for rejection of the material and subject to referee analyses.

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

7.4 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. Chips should be clean and sharp. Samples for analysis should be stored in suitable containers.

8. Mechanical Requirements

8.1 Ensure that the material supplied under this specification conforms to the mechanical property requirements given 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 the specified yield strength, and then the cross-head speed shall be increased so as to produce fracture in approximately one additional minute.

8.3 *Number of Tests*—Perform a minimum of two tension tests from each lot. A lot is defined as the total number of mill products produced from the same heat under the same conditions at essentially the same time. Should either of the two test specimens not meet the specified requirements, test two additional test pieces representative of the same lot in the same manner. The lot will be considered in compliance only if both additional test pieces meet the specified requirements. If a specimen fails outside the gage, the test is null in accordance with Methods E 8, and a retest shall be performed.

9. Special Requirements

9.1 Ensure that the microstructure is martensitic with finely dispersed alpha or beta phases, or both. The alpha or beta phases, or both, may be too fine to be visible metallographically but must be present to ensure adequate strength. No continuous alpha network at prior beta grain boundaries will be present. The microstructure within the prior beta grain boundaries will be acicular. Perform metallographic evaluation in the aged condition.

9.2 Determine the beta transus temperature for each heat by a suitable method and reported on the materials certification, if required by the purchaser.

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

TABLE 1 Chemical Requirements

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

[A] Material 0.032 in. (0.813 mm) and under may have hydrogen content up to 0.015 %.

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

TABLE 2 Product Analysis Tolerance[A]

Element	Tolerance Under the Minimum or Over the Maximum Limit %[B]
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.0020
Iron	0.10
Oxygen	0.02
Niobium	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]

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 (860)	105 000 (725)	8	15
Solution treated	80 000 (550)	50 000 (345)	15	30
Unannealed	80 000 (550)	50 000 (345)	8	15

[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.

[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 must 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 supplier and purchaser. (5.65 square root S_o, where S_o is the original cross sectional area.)

[D] Applies to bar only.