~~Designation:F1713–03~~ Designation: F 1713 – 08

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:* [3]

E 8~~Methods of Tension Testing of Metallic Materials~~ Test Methods for Tension Testing of Metallic Materials

E~~120Test Methods for Chemical Analysis of Titanium and Titanium Alloys~~ 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

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

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity/Infrared Detection Method

E 1941 Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys

E 2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry

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

F 1472 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 Alloys[4]

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

ASQ C1 Specifications of General Requirements for a Quality Program

~~2.4 *ISO Standard:*~~

[5]

2.4 *ISO Standards:*

ISO 5832-3 Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminium 4-Vanadium Alloy[6]

ISO 6892~~Metallic Materials Tensile Testing at Ambient Temperature~~ Metallic Materials Tensile Testing at Ambient Temperature[6]

ISO 9001 Quality Management Systems—Requirements[6]

3. ~~Terminology~~

~~3.1*Definitions of Terms Specific to This Standard:*~~

[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 F1713–96.~~

Current edition approved Feb. 1, 2008. Published March 2008. Originally approved in 1996. Last previous edition approved in 2003 as F 1713 – 03.

[2] The boldface numbers in parentheses refer to the list of references at the end of ~~the text.~~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* ~~, Vol 03.01.~~volume information, refer to the standard's Document Summary page on the ASTM website.

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

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

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

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

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

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

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

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

3.1.1.2Remove from furnace and air cool to room temperature. 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 *solution treated*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 ± 0.25 h at 923 ± 25°F (495 ± 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.

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).

3.1.3

3.1.7 *unannealed*, *n*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. (4.75(4.76 mm) to 4 in. (101.60(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. (75(4.76 mm) in diameter or thickness.

5. Ordering Information

5.1Include with inquiries and orders for material under this specification the following information.

5.1.1Quantity (weight or number of pieces),

5.1.2Applicable ASTM designation,

5.1.3Form (wire or bar),

5.1.4Condition (see Section 3),

5.1.5Mechanical properties (if applicable, for special conditions),

5.1.6Finish (see 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);

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

5.1.8Special tests, and

5.1.9Special requirements.);

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

6.1The 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

6.1 *Finish*—The mill product may be furnished to the implant manufacturer as descaled, pickled, sandblasted, ground, machined, or combinations of these operations. —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

~~7.1Ensure that the~~ 7.1 The heat analysis ~~conforms~~shall conform 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.~~ . 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.

~~7.2Product 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~~

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~~are cause for rejection of the material and subject to referee analyses.~~

~~7.3For referee purposes, use Test Methods E120~~ .

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.

7.2.3 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product analyses. Product analysis outside the tolerance limits allowed in Table 2 shall be cause for rejection of the product. A referee analysis may be used if agreed upon by supplier and purchaser.

7.2.4 For referee purposes, use Test Methods E 1409, E 1447, E 1941, and E 2371 or other analytical methods agreed upon between the purchaser and the supplier.

~~7.4Ensure that the samples~~ 7.3 Samples for chemical analysis ~~are~~ shall be representative of the material being tested. The utmost care ~~must~~shall 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~~Cutting tools should be clean and sharp. Samples for analysis should be stored in suitable containers.

8. Mechanical Requirements

~~8.1Ensure that the~~ 8.1 The material supplied under this specification ~~conforms~~ shall conform to the mechanical property requirements ~~given~~ in Table 3. Alternative properties may be agreed upon between the purchaser and supplier.

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~~may 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 E8, and a retest shall be performed.~~ Number of Tests :

8.3.1 *Bar and Wire*—Perform at least one tension test from each lot in the longitudinal direction. Should the test result not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test piece. The lot shall be considered in compliance only if all additional test pieces meet the specified requirements.

8.3.2 Tensile tests results for which any specimen fractures outside the gage length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. If either the elongation or reduction of area is less than

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.