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Standard Specification for Wrought Zirconium-2.5Niobium Alloy for Surgical Implant Applications (UNS R60901)[1]

This standard is issued under the fixed designation F2384; 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 zirconium-2.5niobium alloy to be used in the manufacture of surgical implants (**1**).[2]

1.2 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in non-conformance with the standard.

2. Referenced Documents

2.1 *ASTM Standards:*[3]

B550/B550M Specification for Zirconium and Zirconium Alloy Bar and Wire

E8/E8M Test Methods for Tension Testing of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E112 Test Methods for Determining Average Grain Size

E1552 Test Method for Determining Hafnium in Zirconium and Zirconium Alloys By Direct Current Plasma—Atomic Emission Spectrometry

E1941 Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis

E2626 Guide for Spectrometric Analysis of Reactive and Refractory Metals

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

SI 10 American National Standard for Use of the International System of Units (SI): The Modern Metric System

2.2 *ISO Standard:*[4]

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems—Requirements

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *annealed, adj*—material that exhibits a recrystalized grain structure.

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

4. Product Classification

4.1 *bar*—rounds, flats or shapes from 4.76 to 101.60 mm [0.1875 to 4 in.] in diameter or thickness (other sizes and shapes by special order).

4.2 *wire*—rounds or flats less than 4.76 mm [0.1875 in.] 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,

5.1.2 ASTM designation and date of issue,

5.1.3 Units to be certified—SI or inch-pound,

5.1.4 Grade (if applicable),

5.1.5 Form (bar, or wire),

5.1.6 Condition (see 6.3),

5.1.7 Mechanical properties (if applicable for special conditions),

5.1.8 Finish (see 6.2),

5.1.9 Applicable dimension including size, thickness, width, or drawing number,

5.1.10 Special tests, if any, and

[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.

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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.

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

5.1.11 Other requirements.

6. Materials and Manufacture

6.1 Materials covered by this specification shall be produced by multiple vacuum melting in arc furnaces, electron beam melting, or other melting processes conventionally used for reactive metals.

6.2 *Finish*—The mill product may be furnished to the implant manufacturer as descaled or pickled, abrasively blasted, chemically milled, ground, machined, peeled, polished, or as specified by the purchaser.

6.3 *Condition*—Barstock shall be furnished in the annealed condition unless otherwise specified.

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, oxygen, and nitrogen. Samples for hydrogen, oxygen and nitrogen shall be taken from the finished mill product. The supplier shall not ship material with chemistry outside the requirements specified in Table 1. Guide E2626 may be used as a guide for chemical analysis techniques.

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:*

7.2.1 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. The 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.

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 analysis.

7.3 For referee purposes, use Test Method E1552 and E1941 or other analytical methods, as agreed upon between the purchaser and the supplier.

TABLE 1 Chemical Requirements

Element	Composition % mass/mass	
	min	max
Niobium	2.40	2.80
Oxygen	0.09	0.13
Carbon	...	0.027
Chromium	...	0.020
Hafnium	...	0.010
Hydrogen	...	0.0025
Iron	...	0.15
Nitrogen	...	0.0080
Tin	...	0.0050
Zirconium	balance[A]	balance[A]

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

TABLE 2 Product Analysis Tolerances

Alloying Element	Permissible Variation from the Specified Range, % mass/mass
Niobium	0.050
Oxygen	0.020
Carbon	0.002
Chromium	0.002
Hafnium	0.002
Hydrogen	0.0005
Iron	0.002
Nitrogen	0.0016
Tin	0.001

7.4 The samples for chemical analysis shall be representative of the material being tested. The utmost care must be used in sampling zirconium 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. Cutting tools should be clean and sharp. Samples for analysis should be stored in suitable containers.

8. Mechanical Requirements

8.1 The material supplied under this specification shall conform to the mechanical property requirements in Table 3.

8.2 Specimens for tension tests shall be machined from bar in the longitudinal direction and tested in accordance with Test Methods E8/E8M. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in./min [mm/mm/min] through yield and then the crosshead speed 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 (see 3.1.2). 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.

8.4 Tension test results for which any specimen fractures outside the gage length shall be considered acceptable, if both the elongation and reduction of area meets the minimum requirements specified. Refer to Test Methods E8/E8M, sections 7.11.4 and 7.11.5. If either the elongation or reduction of area is less than the minimum requirement, discard the test and

TABLE 3 Mechanical Properties[A]

Condition	Tensile Strength, min, MPa [psi]	Yield Strength (0.2 % offset), min, MPa [psi]	Elongation[B] in 2 in. or 4D or 4W, min, %
Annealed	450 [65 000]	310 [45 000]	15

[A] Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and the implant manufacturer.

[B] Elongation of material 1.6 mm [0.063 in.] or greater in diameter (D) or width (W) shall be measured using a gage length of 2 in. or 4D or 4W. The gage length must be reported with the test results. The method for determining elongation of material under 1.6 mm [0.063 in.] in diameter or thickness may be negotiated. Alternately, a gage length corresponding to ISO 6892 may be used when agreed upon by supplier and purchaser. (5.65 $\sqrt{}$So, where So is the original cross sectional area).