



Designation: F2384 – 24

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 are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems shall not be combined.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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

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 May 1, 2024. Published May 2024. Originally approved in 2005. Last previous edition approved in 2016 as F2384 – 10 (2016). DOI: 10.1520/F2384-24.

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.

E112 Test Methods for Determining Average Grain Size

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

IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 ISO Standard:⁴

ISO 6892-1 Metallic Materials—Tensile Testing—Part 1: Method of Test at Room Temperature

ISO 9001 Quality Management Systems—Requirements

ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *annealed, adj*—material that exhibits a recrystallized 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*—Round, rectangular, or other complex shaped product delivered straightened and cut to defined lengths.

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 Mechanical properties (if applicable for special conditions),

5.1.5 Form (bar),

5.1.6 Condition (see 6.3),

5.1.7 Finish (see 6.2),

5.1.8 Applicable dimension including size, thickness, width, and length (exact, random, or multiples) or drawing number,

5.1.9 Special tests, if any, and

5.1.10 Other requirements.

⁴ 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 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 supplier's heat analysis shall conform to the chemical composition prescribed in [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](#).

7.1.1 Requirements for the major and minor elemental constituents are listed in [Table 1](#). Also listed are important residual elements.

7.1.2 All commercial metals may contain small amounts of elements other than those which are specified. It is neither practical nor necessary to specify limits for unspecified elements that can be present. The supplier/producer is permitted to analyze for unspecified elements and is permitted to report such analyses. The presence of an unspecified element and the reporting of an analysis for that element shall not be a basis for rejection unless previously agreed to between supplier and purchaser.

7.1.3 Intentional elemental additions other than those specified in [Table 1](#) are not permitted.

7.1.4 Analysis for elements not listed in [Table 1](#) is not required to verify compliance with this specification.

7.2 *Product (Check) Analysis*—Product (check) 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](#).

TABLE 1 Chemical Requirements, Heat Analysis

Element	Composition % mass/mass	
	min	max
Niobium	2.40	2.80
Oxygen	0.09	0.13
Carbon	...	0.027
Chromium	...	0.020
Cobalt	...	<0.1
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
Cobalt	0.02
Hafnium	0.002
Hydrogen	0.0005
Iron	0.002
Nitrogen	0.0016
Tin	0.001

7.2.1 Product (check) analysis limits are not for the supplier's/producer's use at acceptance testing. Product analysis limits are not permitted to be applied to ladle or ingot analysis. The supplier/producer shall not ship material that is outside the limits specified in [Table 1](#).

7.2.2 A product (check) analysis is one performed by the purchaser or the supplier of the metal after it has been worked into semi-finished or finished forms or fabricated into parts, and 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. In the analysis of finished parts, these values do not apply to elements whose percentage can be varied by fabricating techniques employed (for example oxygen, nitrogen, or hydrogen) unless the sample is sufficiently large to produce a reliable result.

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. Product (check) analysis outside the tolerance limits allowed in [Table 2](#) is cause for rejection of the product. A referee analysis may be used if agreed upon by supplier and purchaser.

7.3 For referee purposes, analytical methods shall be used as agreed upon between the purchaser and the supplier.

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 Tensile Properties:

8.1.1 The mechanical properties of test specimens shall conform to the requirements specified in [Table 3](#).

8.1.2 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.