

Designation: F67 – 13 (Reapproved 2017)

# Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)<sup>1</sup>

This standard is issued under the fixed designation F67; 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 ( $\varepsilon$ ) indicates an editorial change since the last revision or reapproval.

## 1. Scope\*

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for four grades of unalloyed titanium strip, sheet, plate, bar, billet, forging, and wire used for the manufacture of surgical implants.

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.

1.3 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:<sup>2</sup>

- B265 Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate
- B348 Specification for Titanium and Titanium Alloy Bars and Billets
- B381 Specification for Titanium and Titanium Alloy Forgings
- E8/E8M Test Methods for Tension Testing of Metallic Materials
- E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
- E290 Test Methods for Bend Testing of Material for Ductility

- E1409 Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by Inert Gas Fusion
- E1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by Inert Gas Fusion Thermal Conductivity/Infrared Detection Method
- E1941 Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis
- E2371 Test Method for Analysis of Titanium and Titanium Alloys by Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry (Performance-Based Test Methodology)
- E2626 Guide for Spectrometric Analysis of Reactive and Refractory Metals
- F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Insertion into Bone
- IEEE/ASTM SI 10 American National Standard for Metric Practice
- 2.2 Aerospace Material Specification:<sup>3</sup>
- AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys
- AMS 2380 Approval and Control of Premium Quality Titanium Alloys
- AMS 2631 Ultrasonic Inspection Titanium Alloy Bar, Billet and Plate
- 2.3 ISO Standards:
- ISO 5832-2 Implants for Surgery—Metallic Materials— Unalloyed Titanium<sup>4</sup>
- ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature<sup>4</sup>

ISO 9001 Quality Management Systems<sup>4</sup>

### 3. Terminology

3.1 Definitions of Terms Specific to This Standard:

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

<sup>&</sup>lt;sup>1</sup> 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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<sup>&</sup>lt;sup>2</sup> 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.

<sup>&</sup>lt;sup>3</sup> Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001.

<sup>&</sup>lt;sup>4</sup> Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

3.1.2 *cold work, n*—any mechanical deformation process performed below the recrystallization temperature which results in strain hardening of the material.

3.1.3 *hot work, n*—any mechanical deformation process performed above the recrystallization temperature.

3.1.4 *alpha case*, *n*—oxygen, nitrogen or carbon-enriched, alpha-stabilized surface which results from elevated temperature exposure.

### 4. Product Classification

4.1 Product classifications are consistent with Specifications B265, B348, and B381.

4.1.1 *Strip*—Any product 0.188 in. (4.76 mm) and under in thickness and less than 24 in. (610 mm) wide.

4.1.2 *Sheet*—Any product 0.188 in. (4.76 mm) and under in thickness and 24 in. (610 mm) or more in width.

4.1.3 *Plate*—Any product 0.188 in. (4.76 mm) thick and over and 10 in. (254 mm) wide and over, with widths greater than five times thickness. Plate up to 4 in. (102 mm), thick inclusive is covered by this specification.

4.1.4 *Bar*—Rounds, flats, or other shapes from 0.188 in. (4.76 mm) to 4 in. (102 mm) in diameter or thickness. (Other sizes and shapes by special order.)

4.1.5 *Forging bar*—Bar as described in 4.1.4 used in the production of forgings. This product may be furnished in the hot worked condition.

4.1.6 *Billet*—A solid semi-finished section hot rolled or forged from an ingot, with a cross sectional area greater than 16 in.<sup>2</sup> (10 322 mm<sup>2</sup>) whose width is less than 5 times its thickness.

4.1.7 *Forging*—Any product of work on metal formed to a desired shape by impact or pressure in hammers, forging machines, upset presses, or related forming equipment.

4.1.8 *Wire*—Rounds, flats or other shapes less than 0.188 in. (4.76 mm) in diameter or thickness.

4.1.9 *Other*—Other forms and shapes, including tubing, may be provided by agreement between purchaser and supplier.

#### 5. Ordering Information

5.1 Inquiries and orders for material under this specification shall include the following information:

5.1.1 Quantity (weight or number of pieces),

5.1.2 Grade (1, 2, 3, or 4),

5.1.3 ASTM designation and date of issue,

5.1.3.1 Units to be certified – SI or inch-pound,

Element	Specified	aximum of Range %, /mass)	Tolerance Under the Minimum or Over the Maximum Limit <sup>B</sup>	
Nitrogen	up to	0.05	0.02	
Carbon		0.10	0.02	
Hydrogen	up to	0.015	0.0020	
Iron	up to	0.25	0.10	
Iron	over	0.25	0.15	
Oxygen	up to	0.20	0.02	
Oxygen	over	0.20	0.03	

A Refer to AMS 2249.

<sup>B</sup> Under minimum limit not applicable for elements where only a maximum percentage is indicated.

5.1.4 Form (sheet, strip, plate, bar, billet, forging, wire, or other forms),

5.1.5 Condition (see 6.1),

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

5.1.7 Finish (see 6.2),

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

5.1.9 Special tests (if any), and

5.1.10 Other requirements.

#### 6. Manufacture

6.1 *Condition*—Material shall be furnished in the hot-worked, cold-worked, forged, annealed, or stress-relieved condition.

6.2 *Finish*—The mill product may be furnished as descaled or pickled, abrasive blasted, chemically milled, ground, machined, peeled, polished, or as specified by the purchaser. On billets, bars, plates, and forgings, it is permissible to remove minor surface imperfections by spot grinding if such grinding does not reduce the dimension below the minimum permitted by the dimensional tolerance ordered.

## 7. Chemical Composition

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. Samples for hydrogen shall be taken from the finished mill product. Supplier shall not ship material with chemistry outside the requirements specified in Table 1 for the applicable grade.

TABLE 1 Chemical R	equirements
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Element	Composition <sup>A</sup> , % (mass/mass)				
	Grade 1 UNS R50250	Grade 2 UNS R50400	Grade 3 UNS R50550	Grade 4 UNS R50700	
Nitrogen, max	0.03	0.03	0.05	0.05	
Carbon, max	0.08	0.08	0.08	0.08	
Hydrogen, max <sup>B</sup>	0.015	0.015	0.015	0.015	
Iron, max	0.20	0.30	0.30	0.50	
Oxygen, max	0.18	0.25	0.35	0.40	
Titanium	balance	balance	balance	balance	

<sup>A</sup> Forgings are designated Grade F-1, F-2, F-3, or F-4 respectively. Forging compositions are as specified in Table 1.

<sup>B</sup> Maximum hydrogen content for billet is 0.0100 wt%.