



Designation: F67 – 24

Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)¹

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 (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 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 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 Any agreement between the purchaser and supplier must meet the minimum requirements of this specification.

1.4 *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.*

1.5 *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:²

- [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](#)
- [E539 Test Method for Analysis of Titanium Alloys by Wavelength Dispersive X-Ray Fluorescence Spectrometry](#)
- [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 Reactive Metals and Reactive Metal Alloys by Inert Gas Fusion with Detection by Thermal Conductivity or Infrared Spectrometry](#)
- [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 \(Performance-Based Test Methodology\)](#)
- [E2994 Test Method for Analysis of Titanium and Titanium Alloys by Spark Atomic Emission Spectrometry and Glow Discharge Atomic Emission Spectrometry \(Performance-Based Method\)](#)
- [F981 Practice for Assessment of Muscle and Bone Tissue Responses to Long-Term Implantable Materials Used in Medical Devices](#)
- [IEEE/ASTM SI 10 American National Standard for Metric Practice](#)

2.2 Aerospace Material Specifications:³

- [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](#)

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 For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at www.astm.org/contact. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001.

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

2.3 ISO Standards:⁴

ISO 5832-2 Implants for Surgery—Metallic Materials—Unalloyed Titanium

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

ISO 9001 Quality Management Systems

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

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

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

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

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

4.1.4 *Bar*—Rounds, flats, or other shapes from 4.76 mm [0.188 in.] to 102 mm [4 in.] 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 10 322 mm² [16 in.²] whose width is less than 5× 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 4.76 mm [0.188 in.] in diameter or thickness.

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

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.

⁴ Available from American National Standards Institute (ANSI), 1180 Avenue of the Americas, 10th Floor, New York, NY 10036, <http://www.ansi.org>.

TABLE 1 Chemical Requirements

Element	Composition, ^A % (mass/mass)				
	Grade 1 ELI	Grade 1 UNS R50250	Grade 2 UNS R50400	Grade 3 UNS R50550	Grade 4 and 4CW UNS R50700
Nitrogen, max	0.012	0.03	0.03	0.05	0.05
Carbon, max	0.03	0.08	0.08	0.08	0.08
Hydrogen, max ^B	0.0125	0.0125	0.0125	0.0125	0.0125
Iron, max	0.10	0.20	0.30	0.30	0.50
Oxygen, max	0.10	0.18	0.25	0.35	0.40
Cobalt	<0.10	<0.10	<0.10	<0.10	<0.10
Titanium	balance	balance	balance	balance	balance

^A Forgings are designated Grade F-1 ELI, F-1, F-2, F-3, or F-4 respectively. Forging compositions are as specified in **Table 1**.

^B Maximum hydrogen content for billet is 0.0100 wt%.