



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 F 67; 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 inch-pound units are to be regarded as the standard. The SI equivalents in parentheses are for information only.

2. Referenced Documents

2.1 ASTM Standards:²

B 265 Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate

B 348 Specification for Titanium and Titanium Alloy Bars and Billets

B 381 Specification for Titanium and Titanium Alloy Forgings

E 8 Test Methods for Tension Testing of Metallic Materials

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E 290 Test Methods for Bend Testing of Material for Ductility

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

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

2.2 Aerospace Material Specification:

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys³

2.3 ISO Standards:

ISO 5832-2 Implants for Surgery—Metallic Materials—Unalloyed Titanium⁴

ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature⁴

ISO 9001 Quality Management Systems⁴

2.4 American Society for Quality (ASQ) Standard:

C1 Specifications of General Requirements for a Quality Program⁴

3. Terminology

3.1 Definition of Term 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.

4. Product Classification

4.1 Product classifications are consistent with Specifications **B 265**, **B 348**, and **B 381**.

4.1.1 *Strip*—Any product 0.1875 in. (4.76 mm) and under in thickness and less than 24 in. (610 mm) in width.

4.1.2 *Sheet*—Any product 0.1875 in. (4.76 mm) and under in thickness and 24 in. (610 mm) or more in width.

4.1.3 *Plate*—Any product 0.1875 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. (101.60 mm), thick inclusive is covered by this specification.

4.1.4 *Bar*—Rounds, flats, or other shapes from 0.1875 in. (4.76 mm) to 4 in. (101.60 mm) in diameter or thickness. (Other sizes and shapes by special order.)

4.1.5 *Billet*—A solid semi-finished section hot rolled or forged from an ingot, with a cross sectional area greater than 16 in.² (10 322 mm²) whose width is less than 5 times its thickness.

4.1.6 *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.

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 service@astm.org. 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.

⁴ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

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

TABLE 1 Chemical Requirements

Element	Composition ^A , % (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 ^B	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

^A Forgings are designated Grade 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%.

TABLE 2 Product Analysis Tolerances^A

Element	Limit or Maximum of Specified Range %, (mass/mass)	Tolerance Under the Minimum or Over the Maximum Limit ^B
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](#).

^B Under minimum limit not applicable for elements where only a maximum percentage is indicated.

4.1.7 *Wire*—Rounds, flats or other shapes less than 0.1875 in. (4.76 mm) in diameter or thickness.

4.1.8 *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,
- 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, 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*—Unalloyed titanium material shall be free of injurious external and internal imperfections of a nature that will interfere with the purpose for which it is intended. 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,

TABLE 3 Mechanical Requirements: Annealed-Bar, Billet, Forgings, and Other Forms^A

Grade	Tensile Strength, min		Yield Strength, 0.2 % Offset, min		Elongation ^B in 4D, min, %	Reduction of Area, min, % ^C
	ksi	MPa	ksi	MPa		
1	35	240	25	170	24	30
2	50	345	40	275	20	30
3	65	450	55	380	18	30
4	80	550	70	483	15	25

^A These properties apply to forgings having a maximum cross section area not greater than 3 in.² (1935 mm²). Mechanical properties of forgings having greater cross sections shall be negotiated between the manufacturer and the purchaser.

^B Elongation of material 0.063 in. (1.6 mm) or greater in diameter (*D*) or width (*W*) shall be measured using a gauge length of 2 in. or 4*D* or 4*W*. The gauge length must be reported with the test results. The method for determining elongation of material under 0.063 in. (1.6 mm) in diameter or thickness may be negotiated. Alternatively, a gauge length corresponding to [ISO 6892](#) may be used when agreed upon between supplier and purchaser. (5.65 times the square root of *S*_o, where *S*_o is the original cross sectional area.)

^C Reduction of area not required for tubing.

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.

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*—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](#).

7.2.1 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.

7.2.2 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 *Referee Analysis*—If the results of the purchaser's product analysis are outside the limits allowed in [Table 2](#), these

TABLE 4 Mechanical Requirements: Annealed-Sheet, Strip, and Plate

Grade	Tensile Strength, ^A min		Yield Strength, ^A (0.2 % Offset)				Elongation ^B in 2 in. or 50 mm, min,%	Bend Test Mandrel Diameter ^C	
	ksi	MPa	min		max			Under 0.070 in. (1.8 mm) in Thickness	0.070 to 0.187 in. (1.8 to 4.75 mm) in Thickness
			ksi	MPa	ksi	MPa			
1	35	240	25	170	45	310	24	3T	4T
2	50	345	40	275	65	450	20	4T	5T
3	65	450	55	380	80	550	18	4T	5T
4	80	550	70	483	95	655	15	5T	6T

^A Minimum and maximum limits apply to tests taken both longitudinal and transverse to the direction of rolling. Mechanical properties for conditions other than annealed or plate thickness over 1 in. (25 mm) may be established by agreement between the manufacturer and the purchaser.

^B Elongation of material 0.063 in. (1.6 mm) or greater in diameter (*D*) or width (*W*) shall be measured using a gauge length of 2 in. or 4*D* or 4*W*. The gauge length must be reported with the test results. The method for determining elongation of material under 0.063 in. (1.6 mm) in diameter or thickness may be negotiated. Alternatively, a gauge length corresponding to **ISO 6892** may be used when agreed upon between supplier and purchaser. (5.65 times the square root of *S*_o, where *S*_o is the original cross sectional area.)

^C *T* equals the thickness of the bend test specimen; refer to Test Methods **E 290**. Bend tests are not applicable to material over 0.1875 in. (4.75 mm) in thickness.

TABLE 5 Mechanical Requirements: Annealed Wire^A

Diameter, in. (mm)	Grade	Ultimate Tensile Strength, min, ksi (MPa)	Yield Strength, (0.2% offset) min, ksi (MPa)	Elongation ^B min, %	Reduction in Area, min, %
≥0.125 (≥3.18)	1	35 (240)	25 (170)	24	30
	2	50 (345)	40 (275)	20	30
	3	65 (450)	55 (380)	18	30
	4	80 (550)	70 (483)	15	25
<0.125 to 0.062 inclusive (<3.18 to 1.58 inclusive)	1	35 (240)	25 (170)	15	...
	2	50 (345)	40 (275)	12	...
	3	65 (450)	55 (380)	10	...
	4	80 (550)	70 (483)	8	...
<0.062 to 0.020 inclusive (<1.58 to 0.51 inclusive)	1	35 (240)	...	12	...
	2	50 (345)	...	10	...
	3	65 (450)	...	8	...
	4	80 (550)	...	6	...
<0.020 to 0.005 inclusive (<0.51 to 0.13 inclusive)	1	35 (240)	...	10	...
	2	50 (345)	...	8	...
	3	65 (450)	...	6	...
	4	80 (550)	...	4	...

^A Mechanical properties for cold worked condition shall be established by agreement between the supplier and the purchaser.

^B Elongation of material 0.063 in. (1.6 mm) or greater in diameter (*D*) or width (*W*) shall be measured using a gauge length of 2 in. or 4*D* or 4*W*. The gauge length must be reported with the test results. The method for determining elongation of material under 0.063 in. (1.6 mm) in diameter or thickness may be negotiated, or a 10 in. gauge length may be used. Alternatively, a gauge length corresponding to **ISO 6892** may be used when agreed upon between supplier and purchaser. (5.65 times the square root of *S*_o, where *S*_o is the original cross sectional area.)

TABLE 6 Round Wire Size Tolerances

Diameter, in. (mm)	Size Variation, in. (mm)	Out-of-Round, ^A in. (mm)
0.3125 to 0.125 inclusive (7.94 to 3.18 inclusive)	±0.002 (0.051)	0.002 (0.051)
<0.125 to 0.030 inclusive (<3.18 to 0.76 inclusive)	±0.001 (0.025)	0.001 (0.025)
<0.030 to 0.010 inclusive (<0.76 to 0.25 inclusive)	±0.0008 (0.020)	0.0008 (0.020)
<0.010 to 0.005 inclusive (<0.25 to 0.13 inclusive)	±0.0005 (0.013)	0.0005 (0.013)

^A Out-of-Round is the difference between the maximum and minimum diameters of the wire measured at the same cross section.

results may be subject to a referee analysis. For referee purposes, use Test Methods **E 2371**, **E 1409**, and **E 1447** or other analytical methods. Refereeing will be used, if the need for refereeing, the test lab to perform the referee testing, and the referee test method are agreed upon between the supplier and the purchaser.

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

8. Mechanical Requirements

8.1 Bar, billet, and forging shall conform to the mechanical property requirements prescribed in **Table 3**. Sheet, strip, and plate shall conform to the mechanical property requirements prescribed in **Table 4**. Wire products shall conform to the mechanical property requirements prescribed in **Table 5**. Grades may be ordered in the cold-worked condition to higher minimum tensile strength but a minimum 10 % elongation in 4*D* or 2 in. (50 mm) must be met except for wire. See footnotes in **Table 5**.

8.2 For sheet and strip, the bend test specimen shall withstand being bent cold through an angle of 105° without fracture on the outside of the bent portion. The bend shall be made on a diameter equal to that shown in **Table 4** for the applicable grade.

8.3 Tension testing shall be performed in accordance with Test Methods **E 8**. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in. (mm/mm)/min through the specified yield strength, and then the crosshead speed shall be increased so as to produce fracture in approximately one additional minute.

8.3.1 Tension testing of wire shall be conducted in accordance with Test Methods **E 8**. Tension testing shall be conducted using the appropriate gauge length, shown in **Table 5**, for the size wire being tested. For wire sizes ≥ 0.0625 in. (≥ 1.59 mm) (4D gauge length) a strain rate of 0.003 to 0.007 in./in. (mm/mm)/min through the specified yield strength shall be used and then the crosshead speed shall be increased so as to produce fracture in approximately one additional minute. For wire diameters less than 0.0625 in. (1.59 mm) a crosshead speed of 0.5 to 1.0 in./min (12.7 to 25.4 mm/min) shall be used. Once yielding has begun, the crosshead speed may be increased to a maximum of 3.0 in./min (76.2 mm/min).

8.4 Number of Tests:

8.4.1 *Bar, Forging Bar, Shapes, and Wire*—Perform at least one tension test from each lot. Should any of these test pieces 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 both additional test pieces meet the specified requirements.

8.4.2 Tensile tests results for which any specimen fractures outside the gauge length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to Test Method **E 8**, sections 7.11.4 and 7.12.5. If either the elongation or reduction of area is less than the minimum requirement, discard the test and retest. Retest one specimen for each specimen that did not meet the minimum requirements.

8.4.3 *Sheet, Strip, and Plate*—Perform at least one tension and at least one bend test for both longitudinal and transverse directions from each lot. Tests in the transverse direction need

be made only on product from which a specimen not less than 8.0 in. (200 mm) in length for sheet, and 2.50 in. (64 mm) in length for plate can be taken. Should any of these test pieces 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 both additional test pieces meet the specified requirements.

9. Special Requirements

9.1 Alpha case is not permitted when viewed at 100 \times magnification.

9.2 Size variation and out-of-round tolerances for round wire shall meet the requirements specified in **Table 6**.

10. Significance of Numerical Limits

10.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right hand digit used in expressing the specification limit, in accordance with the rounding method of Practice **E 29**.

11. Certification

11.1 The supplier shall provide a certification that the material was tested in accordance with this specification and met all requirements. A report of the test results shall be furnished to the purchaser at the time of shipment.

11.2 Gauge length must be reported with elongation.

12. Quality Program Requirements

12.1 The supplier shall maintain a quality program such as defined in ASQ **C1** or ISO 9001.

13. Keywords

13.1 metals (for surgical implants); orthopaedic medical devices; titanium alloys; titanium/titanium alloy; titanium/titanium alloys (for surgical implants)

APPENDICES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the chemical, mechanical, and metallurgical properties of wrought unalloyed titanium to be used in the manufacture of surgical implants.

X1.2 The choice of composition and mechanical properties is dependent upon the design and application of the medical device.

X1.3 ISO standards are listed for reference only. Although the **ISO 5832-2** standard listed in section 2.3 is similar to the corresponding ASTM standards, it is not identical. Use of the

ISO standard instead of the preferred ASTM standards may be agreed upon between the purchaser and supplier.

X1.4 The 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 material is usually multiple melted in arc furnaces (including furnaces such as plasma arc and electron beam) of a type used for reactive metals.

X1.5 The number of samples required in 8.4.1 and 8.4.3 are not intended to represent a statistically valid sample of the lot.

The number of samples required represents a sampling plan with balanced cost and benefit that has served suppliers and purchasers in this market for over 10 years. More frequent sampling may be performed as agreed between supplier and purchaser.

X2. BIOCOMPATIBILITY

X2.1 The unalloyed titanium compositions covered by this specification have been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the well characterized level of biological response exhibited by these unalloyed titanium materials, they have been used as control materials in Practice F 981.

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. Long term clinical experience of the use of the materials referred to in this specification, however, has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F 67 – 00) that may impact the use of this standard. (Approved June 1, 2006.)

- (1) Expanded coverage of specification to include wire products by addition of Mechanical Property Requirements and Size Tolerances (Tables 5 and 6 respectively). Wire tolerances in Table 6 have been modified from those in Specification F 1341.
- (2) Test Methods E 120 has been replaced by Test Method

- E 2371 due to Test Methods E 120 being withdrawn.
- (3) Removed Supplementary Requirement S1 relating to bend testing because it conflicted with Table 4.
- (4) Editorial corrections have been made in order to meet terminology and formatting guidelines established for implant material standards.

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