Designation: F 67 – 00

Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)[1,2]

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 used for the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard.

2. Referenced Documents

2.1 *ASTM Standards:*

B 265 Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate[3]

B 348 Specification for Titanium and Titanium Alloy Bars and Billets[3]

B 381 Specification for Titanium and Titanium Alloy Forgings[3]

E 8 Test Methods for Tension Testing of Metallic Materials[4]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[5]

E 290 Test Method for Semi-Guided Bend Test for Ductility of Metallic Materials[4]

E 527 Practice for Numbering Metals and Alloys[6]

E 1409 Test Method for Determination of Oxygen in Titanium Alloys by the Inert Gas Fusion Technique[7]

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method[7]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[8]

F 1341 Specification for Unalloyed Titanium Wire for Surgical Implant Applications[8]

2.2 *Aerospace Material Specification:*

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys[9]

2.3 *American Society for Quality (ASQ) Standard:*

C1 Specifications of General Requirements for a Quality Program[10]

2.4 *Society of Automotive Engineers Standard:*

SAE J1086 Practice for Numbering Metals and Alloys (UNS)[9]

3. Product Classification

3.1 Product classifications are consistent with Standard Specifications B 265, B 348 and B 381.

3.1.1 *Strip*—Any product 0.1875 in. (4.75 mm) and under in thickness and less than 24 in. (610 mm) in width.

3.1.2 *Sheet*—Any product 0.1875 in. (4.75 mm) and under in thickness and 24 in. (610 mm) or more in width.

3.1.3 *Plate*—Any product 0.1875 in. (4.75 mm) in thickness and over 10 in. (254 mm) in width.

3.1.4 *Bar*—A hot rolled, forged, or cold worked semi-finished solid section product whose cross sectional area is equal to or less than 16 $in.^2$(10322 mm^2); rectangular bar must be less than or equal to 10 in. (254 mm) in width and greater than 0.1875 in. (4.75 mm) in thickness.

3.1.5 *Billet*—A solid semi-finished section hot rolled or forged from an ingot, with a cross sectional area greater than 16 in^2(10322 mm^2) whose width is less than 5 times its thickness.

3.1.6 *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.

3.1.7 *Wire*—Coiled round and non-round product with a diameter or major dimension equal to or greater than 0.3130 in.

NOTE 1—Wire less than or equal to 0.3125 in. in diameter or major dimension is covered in ASTM F 1341.

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

4. Ordering Information

4.1 Inquiries and orders for material under this specification

[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] New UNS designation established in accordance with E 527 and SAE J1086.

[3] *Annual Book of ASTM Standards*, Vol 02.04.

[4] *Annual Book of ASTM Standards*, Vol 03.01.

[5] *Annual Book of ASTM Standards*, Vol 03.05.

[6] *Annual Book of ASTM Standards*, Vol 1.01.

[7] *Annual Book of ASTM Standards*, Vol 3.06.

[8] *Annual Book of ASTM Standards*, Vol 13.01.

[9] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.

[10] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

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%.

shall include the following information:

4.1.1 Quantity (weight or number of pieces),

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

4.1.3 ASTM designation,

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

4.1.5 Condition (5.1),

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

4.1.7 Finish (5.2),

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

4.1.9 Special tests, and

4.1.10 Special requirements.

5. Manufacture

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

5.2 *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. Material may be furnished as descaled, as pickled, as sandblasted, or as ground, or combinations of these operations. The manufacturer shall be permitted 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.

6. Chemical Composition

6.1 The heat analysis shall conform to the requirements as to chemical composition prescribed in Table 1. Ingot analysis may be used for reporting all chemical requirements except hydrogen, samples of which shall be taken from the finished product. Supplier shall not ship material that is outside the limits specified in Table 1 for the applicable grade.

6.1.1 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.

6.2 *Product Analysis*—The product analysis is either for the purpose of verifying the composition of a heat or lot or to determine variations in the composition within the heat.

6.2.1 Acceptance or rejection of a heat or lot of material may be made by the purchaser on the basis of this product analysis.

6.2.2 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. Product analysis limits shall be as specified in Table 2

6.3 For referee purposes, Test Methods E 120, E 1409 and E 1447 shall apply.

6.3.1 Samples for chemical analysis shall be representative of the material being tested.

NOTE 2—**Precaution:** Extreme care must be taken in sampling titanium for chemical analysis because of its affinity for elements such as oxygen, nitrogen, and hydrogen. Therefore, when cutting samples for analysis, the operation should be carried out in a dust-free atmosphere, if possible. Chips should be collected from clean metal. Cutting tools should be clean and sharp. Samples for analysis should be stored in suitable containers.

7. Mechanical Requirements

7.1 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. 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.

7.2 For sheet and strip, the bend test specimen shall withstand being bent cold through an angle of 105° without fracture in 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.

7.2.1 Supplementary bend test requirements for sheet and plate are listed in S1.

7.3 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.

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.

TABLE 3 Mechanical Requirements: Annealed-Bar, Billet, Forging, Wire and Other Forms[A]

Grade	Tensile Strength, min		Yield Strength, 0.2 % Offset, min		Elongation in 4*D*, min, %	Reduction of Area, min, %[B]
	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 mm ^{2}). Mechanical properties of forgings having greater cross sections shall be negotiated between the manufacturer and the purchaser.
[B] Reduction of area not required for tubing.

7.4 Any other special requirements shall be specified on the purchase order.

8. Certification

8.1 The manufacturer's certification that the material was manufactured and tested in accordance with this specification together with a report of the test results shall be furnished to the purchaser at the time of shipment.

9. Quality Program Requirements

9.1 The producer shall maintain a quality program, such as, for example, is defined in ASQ C1.

9.2 Purchaser shall be ensured of the producer's quality program conforms to the intent of ASQ C1, or other recognized program.

10. Keywords

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

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

Grade	Tensile Strength,[A] min		Yield Strength,[A] (0.2 % Offset)				Elongation in 2 in. or 50 mm, min,%	Bend Test[B]	
	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	3*T*	4*T*
2	50	345	40	275	65	450	20	4*T*	5*T*
3	65	450	55	380	80	550	18	4*T*	5*T*
4	80	550	70	483	95	655	15	5*T*	6*T*

[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] *T* equals the thickness of the bend test specimen. Bend tests are not applicable to material over 0.1875 in. (4.75 mm) in thickness.

SUPPLEMENTARY REQUIREMENTS

These requirements shall apply only when specified in the purchase order, in which event the specified tests shall be made by the manufacturer before shipment of the sheets or plates.

S1. Surface Requirements Bend Tests

S1.1 The purpose of this test is to measure the cleanliness or ductility, or both, of the metal surface.

S1.2 Two-guided or free-bend tests of sheet or plate material limited to Grades 1, 2, and 3 shall be made. Each of these bends will place opposite surfaces of the sheet or plate material in tension.

S1.3 The bends are to be made in accordance with Test Method E 290, except that the welds mentioned in these standards are not required. The bend specimen may be of less than full material thickness; however, the outer surface of the specimen must be representative of the product as supplied.

S1.4 The bend radius will be such to provide minimum elongation of the outer fibers of the bent specimen as follows:
Grade 1—20 % equivalent to 2T bend radius at 180° bend
Grade 2—20 % equivalent to 2T bend radius at 180° bend
Grade 3—16 % equivalent to 2½ T bend radius at 180° bend

S1.5 Criteria for acceptance will be the absence of any cracking or surface separations (not originating at the edge of specimen).

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this standard is to characterize composition and properties to ensure consistency in the starting material used directly or as modified by forging in the manufacture of medical devices.

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

X1.3 Table 1 was condensed to have the same chemical requirements for flat product and bars and billet. This is consistent with current commercial practice for unalloyed titanium.

X2. BIOCOMPATIBILTY

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.