Designation: F 1341 – 99

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

This standard is issued under the fixed designation F 1341; 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 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 values given in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards:*

E 8 Test Methods for Tension Testing of Metallic Materials[3]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[4]

E 527 Practice for Numbering Metals and Alloys (UNS)[5]

E 1409 Test Method for Determinitation of Oxygen in Titanium Alloys by the Inert Gas Fusion Technique[4]

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method[6]

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications[7]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[7]

2.2 *Aerospace Material Specification:*

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys[8]

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

C1 Specifications of General Requirements for a Quality Program[9]

2.4 *Society of Automotive Engineers Standard:*

SAE J1086 Practice for Numbering Metals and Alloys (UNS)[8]

3. Product Classification

3.1 *Wire*—Round product with a diameter equal to or less than 0.3125 in. (7.94 mm). Flat and special shape wire with a major dimension equal to or less than 0.3125 in. (7.94 mm) may also be ordered as agreed upon between the supplier and the purchaser.

4. Ordering Information

4.1 Inquiries and orders for material under this specification 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 (wire),

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 including size, thickness, width, spool size, coil diameter, and length (exact, random, multiples) or print number, and

4.1.9 Special Tests, if any.

5. Manufacture

5.1 *Condition*—Material shall be furnished in the annealed or cold worked condition.

5.2 *Finish*—Types of finish available for wire products are bright annealed, pickled, cold drawn, cold rolled, ground, ground and polished, or as specified in the purchase order.

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. The supplier shall not ship material that is outside the limits specified in Table 1 for the applicable grade.

6.1.1 Requirement 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.

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

[2] This specification is under the jurisdiction of ASTM Committee F-04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Resources.

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

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

[5] *Annual Book of ASTM Standards*, Vol 01.01.

[6] *Annual Book of ASTM Standards*, Vol 03.06.

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

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

[9] Available from American Society for Quality, 1611 E. Wisconsin Ave., Milwaukee, WI 53203.

TABLE 1 Chemical Requirements

Element	Composition (wt %)			
	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	0.10	0.10	0.10	0.10
Hydrogen, max	0.0125	0.0125	0.0125	0.0125
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

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

6.2.1 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.

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

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. **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 Annealed round wire shall conform to the appropriate requirements as to mechanical properties prescribed in Table 3. Material may be ordered in the cold worked condition to higher ultimate tensile strengths and lower elongation levels as agreed upon between the supplier and the purchaser.

7.2 Tension testing shall be performed in accordance with Test Method E 8. Tensile properties shall be determined as listed in Table 3 using the appropriate gage length for the wire size being tested. For wire diameters 0.3125 to 0.062 in. (7.93 to 1.57 mm) (4D gage 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 0.062 in. a crosshead speed of 0.5 to 1.0 in./min (12.7 to 25.4 mm) shall be used. Once yielding has begun the crosshead speed may be increased to a maximum of 3.0 in./min. (76.2 mm).

TABLE 2 Product Analysis Tolerances[A]

Element	Limit or Maximum of Specified Range, %	Tolerance Under the Minimum or Over the Maximum Limit[B]
Nitrogen	Up to 0.05	0.02
Carbon	Up to 0.10	0.02
Hydrogen	Up to 0.0125	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 2249C.

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

TABLE 3 Annealed Wire Mechanical Requirements

Diameter, in. (mm)	Grade	Ultimate Tensile Strength, min, ksi (MPa)	Yield Strength, (0.2 % offset), min, ksi (MPa)	Elongation[A,B,C] min, %	Red. in Area min, %
0.3125 to 0.125	1	35 (240)	25 (170)	24	30
(7.938 to 3.175)	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	1	35 (240)	25 (170)	15	...
(<3.175 to 1.575)	2	50 (345)	40 (275)	12	...
	3	65 (450)	55 (380)	10	...
	4	80 (550)	70 (483)	8	...
<0.062 to 0.020	1	35 (240)	...	12	...
(<1.575 to 0.508)	2	50 (345)	...	10	...
	3	65 (450)	...	8	...
	4	80 (550)	...	6	...
<0.020 to 0.005	1	35 (240)	...	10	...
(<0.508 to 0.127)	2	50 (345)	...	8	...
	3	65 (450)	...	6	...
	4	80 (550)	...	4	...

[A] Report gage length on certification.

[B] 2 in. (50 mm) or 4D gage length for diameters 0.3125 to 0.062 in. (7.938 to 1.575 mm).

[C] 10 in. (250 mm) gage length for diameters <0.062 in. (<1.575 mm).

7.3 Any other special tests shall be specified on the purchase order.

8. Special Requirements

8.1 Size variation and out-of-round tolerance for round wire shall meet the requirements specified in Table 4.

9. Certification

9.1 The supplier'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.

10. Quality Program Requirements

10.1 The supplier shall maintain a quality program, such as defined in ASQ C1.

TABLE 4 Round Wire Size Tolerance

Diameter, in. (mm)	Size Variation, in., (mm)	Out-Of-Round,[A] in., (mm)
0.3125 to 0.250 (7.983 to 6.350)	±0.005 (0.127)	0.008 (0.203)
<0.250 to 0.125 (<6.350 to 3.175)	±0.003 (0.076)	0.005 (0.127)
<0.125 to 0.030 (<3.175 to 0.762)	±0.002 (0.051)	0.003 (0.076)
<0.030 to 0.020 (<0.762 to 0.508)	±0.001 (0.025)	0.0008 (0.020)
<0.020 to 0.010 (<0.508 to 0.254)	±0.001 (0.025)	0.0006 (0.015)
<0.010 to 0.005 (<0.254 to 0.127)	±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.

10.2 The purchaser shall be assured of the producer's quality program for conformance to the intent of ASQ C1-1985, or other recognized program.

11. Keywords

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

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this standard is to characterize composition and properties to assure consistency in the starting wire material used 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 Added UNS designations and biocompatibility statements.

X2. BIOCOMPATIBILITY

X2.1 The alloy 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 alloys, they have been used as control materials (Specification F 67) 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.