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Standard Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150)[1]

This standard is issued under the fixed designation F2066; 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 wrought titanium-15 molybdenum alloy to be used in the manufacture of surgical implants (**1**).[2]

1.2 The ~~SI units in this standard are the primary units. The~~ values stated in either ~~primary~~ SI units or ~~secondary~~ inch-pound units are to be regarded separately as standard. The values stated in each system ~~may not be~~are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of each ~~other. Combining~~other, and values from the two systems ~~may result in non-conformance with the standard.~~shall not be combined.

1.3 *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.*

1.4 *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:*[3]

E8/E8M Test Methods for Tension Testing of Metallic Materials
E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
E112 Test Methods for Determining Average Grain Size
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)

[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] The boldface numbers in parentheses refer to the list of references at the end of this standard.

[3] 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.

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

E2994 Test Method for Analysis of Titanium and Titanium Alloys by Spark Atomic Emission Spectrometry and Glow Discharge Atomic Emission Spectrometry (Performance-Based Method)
F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)
F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices
F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Insertion into Bone
F1408 Practice for Subcutaneous Screening Test for Implant Materials
IEEE/ASTM SI 10 American National Standard for ~~Use of the International System of Units (SI): The Modern Metric System~~Metric Practice

2.2 *Aerospace Material Specifications:*[4]
AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys
AMS 2631 Ultrasonic ~~Inspection — Titanium~~ Inspection—Titanium and Titanium Alloy Bar and Billet
AMS 2380 Approval and Control of Premium Quality Titanium Alloys

2.3 *ISO Standards:*[5]
ISO ~~6892~~6892-1 Metallic ~~Materials — Tensile~~ Materials—Tensile Testing at Ambient Temperature
ISO 9001 Quality Management Systems Requirements

~~2.4 *American Society for Quality Standard:*~~
~~ASQ C1 Specification of General Requirements for a Quality Control Program~~[6]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *alpha + beta annealed, n*—the condition of the material that is obtained if, following the final hot-working or cold-working operation, the mill product may be rapidly quenched, for example, by water quenching or pressurized helium gas, from a temperature below the beta transus of approximately ~~750°C [1382°F].~~750 °C [1382 °F].

3.1.2 *alpha + beta annealed + aged, n*—the condition of the material that is obtained by reheating the alpha + beta annealed material to a time-temperature combination below the beta transus to increase the strength of the alloy.

3.1.3 *beta annealed, n*—the condition of the material that is obtained if, following the final hot-working or cold-working operation, the mill product is rapidly quenched, for example, by water quenching or pressurized helium gas quench, from a temperature above the beta transus of approximately ~~750°C [1382°F].~~750 °C [1382 °F].

3.1.4 *beta transus, n*—the minimum temperature at which the ~~alpha plus beta~~ alpha-plus-beta phase can transform to 100 % beta phase.

4. Product Classification

4.1 *Strip*—Any product under 4.76 mm [0.1875 in.] in thickness and under 610 mm [24 in.] wide.

4.2 *Sheet*—Any product under 4.76 mm [0.1875 in.] in thickness and 610 mm [24 in.] or more in width.

4.3 *Plate*—Any product 4.76 mm [0.1875 in.] thick and over and 254 mm [10 in.] wide and over, with a width greater than five times the thickness. Any plate up to 101.60 mm ~~[4 in.], thick~~ [4 in.] thick, inclusive, is covered by this specification.

4.4 *Bar*—~~Rounds, flats, or other shapes from 4.76 mm [0.1875 in.] to 101.60 mm [4 in.] in diameter or thickness. (Other sizes and shapes by special order.)~~Round, rectangular, or other complex-shaped product delivered straightened and cut to defined lengths.

4.5 *Forging Bar*—Bar as described in 4.4 used for production of forgings, may be furnished in the ~~hot worked~~ hot-worked condition.

[4] Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.
[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

4.6 *Wire*—~~Rounds, flats,~~Round, rectangular, or other ~~shapes less than 4.76 mm [~~complex shapes of uniform cross section along~~¾₁₆ in.] in diameter or thickness.~~its entire length furnished in coils, or on spools, reels, or other packaging as specified.

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

5. Ordering Information

5.1 Include with inquiries and orders for material under this specification the following information.

5.1.1 Quantity,

5.1.2 Applicable ASTM designation and date of issue,

5.1.3 Form (strip, sheet, plate, bar, forging bar, wire, other),

5.1.4 Condition (see Section 3 and 6.2),

5.1.5 Mechanical properties (if applicable for special conditions),

5.1.6 Finish (see 6.1),

5.1.7 Applicable dimensions including size, thickness, width, length, or drawing number,

5.1.8 Unit of measurement,

5.1.9 Special tests, if any, and

5.1.10 Special requirements.

6. Materials and Manufacture

6.1 *Finish*—The mill product may be furnished to the implant manufacturer as descaled or pickled, abrasive-blasted, chemically milled, ground, machined, peeled, polished, combinations of these operations, or as specified by the purchaser. On billets, bars, plates, and forgings, it is permissible to remove minor surface imperfections by localized grinding if the resultant area meets the dimensional and surface finish requirements of this specification.

6.2 *Condition:*

6.2.1 *Beta Annealed*—Material shall be furnished in the beta annealed condition. Two classes of beta annealed sheet, strip, and plate are available. If no class is chosen, Class 1 product shall be provided.

6.2.2 *Alpha + Beta Annealed*—Material shall be furnished in the alpha + beta annealed condition.

6.2.3 *Alpha + Beta Annealed + Aged*—Material shall be furnished in the alpha + beta annealed + aged condition.

7. Chemical Requirements

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, and the supplier shall not ship material with chemistry outside the requirements specified in Table 1.

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.~~

7.1.2 All commercial metals may contain small amounts of elements other than those which are specified. It is neither practical, nor necessary, to specify limits for unspecified elements that can be present. The producer is permitted to analyze for unspecified

TABLE 1 Chemical Requirements

Element	Composition, %, (Mass/Mass)
Nitrogen, max	0.05
Carbon, max	0.10
Hydrogen, max	0.015
Iron, max	0.10
Oxygen, max	0.20
Cobalt[A]	<0.1
~~Molybdenum~~	~~14.00-16.00~~
Molybdenum	14.00–16.00
~~Titanium[A]~~	~~balance~~
Titanium[B]	balance

[A] Refer to X1.7.
[B] Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage titanium content by difference is not required to be reported.

elements and is permitted to report such analyses. The presence of an unspecified element and reporting of an analysis for that element shall not be a basis for rejection unless previously agreed to between purchaser and supplier.

7.1.3 Intentional elemental additions other than those specified in Table 1 are not permitted.

7.1.4 Analysis for elements not listed in Table 1 is not required to verify compliance with this specification, unless previously agreed to between purchaser and supplier.

7.1.5 Cobalt content must be reported. Refer to X1.7.

7.2 *Product (Check) Analysis:*

7.2.1 Product ~~analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. The manufacturer~~check analysis limits are not for producer's use as supplier's/producer's acceptance testing. Product analysis limits are not permitted to be applied to ladle or ingot analysis. The supplier/producer shall not ship material ~~that is~~ outside of the limits specified in Table 1. ~~The product analysis~~Given in Table 2 ~~tolerances shall conform to the product tolerances in~~is the amount an individual determination for a ~~Table 2.~~specified element may vary under or over the specified composition limit. In no case shall the several determinations of any element in a heat, using the same analytical procedure, vary both above and below the specified range.

7.2.2 The product ~~analysis is~~ (check) analysis is one performed by purchaser or supplier of the metal after it has been worked into one of the forms specified in Section 4 and 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.

7.2.3 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product (check) analysis. Product (check) analyses outside the ~~tolerance~~variation limits allowed in Table 2 are cause for rejection of the product. A referee analysis may be used if agreed upon by the supplier and purchaser.

TABLE 2 Product ~~Analysis Tolerances~~(Check) Analysis Variation Limits[A]

Element	~~Tolerance~~Variation Under the Minimum or Over the Maximum Limit,[B] ~~, %,~~ % (Mass/Mass)
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.0020
Iron	0.10
Oxygen	0.02
Cobalt	0.02
Molybdenum	0.25

[A] Refer to AMS 2249.
[B] Under the minimum limit not applicable for elements in which only a maximum percentage is indicated.

7.2.4 For referee purposes, use Test ~~Methods,~~Methods E539, E1409, E1447, E1941, E2994, and E2371 or other analytical methods agreed upon between the purchaser and the supplier.

7.3 Samples for chemical analysis are representative of the material being tested. The utmost care must be used in sampling titanium for chemical analysis because of its ~~affinity for~~ ability to react with 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 The material supplied under this specification shall conform to the mechanical property requirements in Table 3 or Table 4.

8.2 Specimens for tension tests shall be machined and tested in accordance with Test Methods E8/E8M. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 ~~in./in./min [mm/mm/min]~~mm/mm/min [in./in./min] through the specified yield and then the crosshead speed shall be increased so as to produce fracture in approximately one additional minute.

8.3 For sheet and strip, the bend test specimen shall withstand being bent cold through an angle of 105° without fracture in the outside surface of the bend portion. The bend shall be made over a mandrel with a diameter equal to that shown in Table 4. Test conditions shall conform to Test Method E290.

8.4 *Number of Tests:*

8.4.1 *Bar, Forging Bar, Shapes, and Wire*—~~Test according to Test Methods E8/E8M.~~ Perform at least one tension test from ~~each~~the lot in the longitudinal direction. Should any test specimen not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test specimen. The lot shall be considered in compliance only if all additional test pieces meet the specified requirements.

8.4.2 Tensile test results for which any specimen fractures outside the gauge length shall be considered acceptable if both the elongation and the reduction of area meet the minimum requirements ~~specified.~~ specified and all other results conform to Table 3. Refer to ~~sections~~subsections 7.11.4 and 7.12.5 of Test Methods E8/E8M. 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*—~~Test according to Test Methods E8/E8M.~~ Perform at least one tension test from each lot in the longitudinal direction. Perform at least one bend test from each lot in both the longitudinal and transverse directions. Tests in the transverse direction need be made only on product from which a specimen not less than ~~200 mm (8.0 in.)~~ 200 mm [8.0 in.] in length for sheet, and 64 mm ~~(2.50 in.)~~[2.50 in.] 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 specimen. The lot shall be considered in compliance only if all additional test pieces meet the specified requirements.

9. Dimensions, Mass, and Permissible Variations

9.1 *Units of Measure:*

TABLE 3 Mechanical Properties—Bar and Wire

Condition[A]	Ultimate Tensile Strength, min, MPa [psi]	Yield Strength (0.2 % Offset), min, MPa [psi]	Elongation[B] in 50 mm [2 in.] 4D or 4W, min, %	Reduction of Area, min, %
Beta Annealed	690 [100 000]	483 [70 000]	20	60
Alpha + Beta Annealed[C,D]	900 [130 500]	800 [116 000]	10	25
Alpha + Beta Annealed + Aged	1150 [166 750]	1050 [152 250]	10	25

[A] Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and purchaser.
[B] Elongation of material 1.6 mm [0.063 in.] or greater in diameter (D) or width (W) shall be measured using a gauge length of 50 mm [2 in.] or 4D or 4W. The gauge length must be reported with the test results. The method for determining elongation of material under 1.6 mm [0.063 in.] in diameter or thickness may be negotiated. Alternatively, a gauge length corresponding to ISO 6892 may be used when agreed upon between the supplier and purchaser. (5.65 times the square root of So, where So is the original ~~cross sectional~~ cross-sectional area.) The gauge length shall be reported with the elongation value.
[C] Mechanical properties for the hot rolled condition may be established by agreement between the supplier and purchaser.
[D] Up to ~~101.60 mm [4.00 in.]~~ 101.60 mm [4.00 in.] diameter or thickness.

TABLE 4 Mechanical Properties—Sheet, Strip, and Plate[A]

Condition[A]	Ultimate Tensile Strength, min, MPa [psi]	Yield Strength (0.2 % Offset), min, MPa [psi]	Elongation[C] in 50 mm [2 in.], min, %	Bend Test Mandrel Diameter[B]	
				Under 1.78 mm [0.070 in.] in Thickness	1.78 to 4.76 mm [0.070 to 0.1875 in.] in Thickness
Beta Annealed, Class 1	724 [105 000]	552 [80 000]	12	5T	6T
Beta Annealed, Class 2	690 [100 000]	483 [70 000]	20	5T	6T

[A] Mechanical properties for conditions other than those listed in this table may be established by agreement between the supplier and purchaser.
[B] T equals the thickness of the bend test specimen. Bend tests are not applicable to material over 4.76 mm [0.1875 in.] in thickness. The limits listed apply to tests taken both longitudinally and transversely to the direction of rolling.
[C] Elongation of material 1.6 mm [0.063 in.] or greater in diameter (D) or width (W) shall be measured using a gauge length of 50 mm [2 in.] or 4D or 4W. The gauge length must be reported with the test results. The method for determining elongation of material under 1.6 mm [0.063 in.] 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 So, where So is the original ~~cross sectional~~ cross-sectional area.) The gauge length shall be reported with the elongation value.

9.1.1 *Selection*—This specification requires that the purchaser select the units (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

9.1.1.1 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

9.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's PO, specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification.

9.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.

9.1.2 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. ~~IEEE/ASTM~~IEEE/ASTM SI 10 ~~SI 10~~ provides guidelines for the use of SI units. Annex A of ~~that~~IEEE/ASTM SI 10 ~~standard~~ provides conversion tables and Annex B of IEEE/ASTM SI 10 provides rules for conversion and significance.

10. Special Requirements

10.1 *Microstructure:*

10.1.1 *Beta Annealed*—The microstructure shall consist of a fully recrystallized beta phase structure. Primary alpha and alpha prime (also known as martensitic alpha) are not permitted in the microstructure when viewed at 100× magnification. The grain size in the annealed condition shall be 5 or finer, in accordance with Test Methods E112.

10.1.2 *Alpha + Beta*—The microstructure shall be a fine dispersion of the alpha and beta phases resulting from processing in the ~~alpha plus beta~~ alpha-plus-beta field. There shall be no continuous alpha network at prior beta grain boundaries. There shall be no coarse, elongated alpha platelets.

10.2 Determine the beta transus temperature for each heat by a suitable method and report on the material certification if required by the purchaser.

10.3 Alpha case is not permitted for products supplied with a machined, ground, or chemically milled surface finish. For other products, there will be no continuous layer of alpha case >0.025 mm [0.001 in.] when examined at 100× magnification.

11. Ultrasonic Inspection

11.1 All centerless ground or peeled and polished round bar >9.5 mm [0.375 in.] in nominal diameter shall be ultrasonically inspected at final diameter according to AMS 2631, Class A1. Equivalent test methods may be substituted when agreed upon by the purchaser and supplier.

NOTE 1—AMS 2631 contains varying flat bottom hole (FBH) requirements based on melting grades per AMS 2380. Since the FBH requirement for Class ~~1~~A1 is the same, regardless of the melting grade, it is not necessary to specify the melting grade.

12. Significance of Numerical Limits

12.1 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 E29.

13. Certification

13.1 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.

14. Quality Program Requirements

14.1 The supplier shall maintain a quality program such as defined in ~~ASQ C1, ISO 9001,~~ ISO 9001 or similar quality ~~program.~~management system.

14.2 The purchaser may audit the producer's quality management system for conformance to the intent of ISO 9001 or other recognized quality management system.

15. Keywords

15.1 metals (for surgical implants); orthopaedic medical devices; titanium alloys; titanium alloys (for surgical implants)

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the chemical, mechanical, and metallurgical properties of wrought titanium-15 molybdenum alloy to be used in the manufacture of surgical implants (**1-4**).

X1.2 The microstructural requirements contained in this specification represent current general consensus with respect to optimization of mechanical properties for implant applications.

X1.3 The minimum mechanical properties specified ensure a baseline of strength and ductility for the highly stressed devices for which this alloy is typically used.

X1.4 The stress corrosion cracking resistance of this alloy is similar to that of titanium-6 aluminum-4 vanadium ELI alloy (**5**).

X1.5 ISO standards are listed for reference only. Use of the ISO standard instead of the preferred ASTM standards may be agreed upon between the purchaser and supplier. ISO 9001 is listed as example only. The inclusion in Section 14 does not indicate mandatory conformance to the example quality standard.