



Designation: F2066 – 23

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 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 each other, and values from the two systems 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)

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 Metric Practice

2.2 Aerospace Material Specifications:⁴

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 2631 Ultrasonic Inspection—Titanium and Titanium Alloy Bar and Billet

AMS 2380 Approval and Control of Premium Quality Titanium Alloys

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.

⁴ Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

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

2.3 ISO Standards:⁵

ISO 6892-1 Metallic Materials—Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems Requirements

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].

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].

3.1.4 *beta transus, n*—the minimum temperature at which the 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, inclusive, is covered by this specification.

4.4 *Bar*—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 condition.

4.6 *Wire*—Round, rectangular, or other complex shapes of uniform cross section along 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.

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 elements and is permitted to report such analyses. The presence of an unspecified element and

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
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.

⁵ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.