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## Standard Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150)<sup>1</sup>

This standard is issued under the fixed designation F 2066; 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 reappraisal. A superscript epsilon ( $\epsilon$ ) indicates an editorial change since the last revision or reappraisal.

### 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).<sup>2</sup>

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:

E 8 Test Methods for Tension Testing of Metallic Materials<sup>3</sup>

E 112 Test Methods for Determining the Average Grain Size<sup>3</sup>

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys<sup>4</sup>

E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique<sup>5</sup>

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method<sup>5</sup>

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications<sup>6</sup>

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices<sup>6</sup>

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone<sup>6</sup>

F 1408 Practice for Subcutaneous Screening Test for Implant Materials<sup>6</sup>

#### 2.2 Aerospace Material Specification:

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys<sup>7</sup>

#### 2.3 American Society for Quality Standard:

ASQ C1 Specification of General Requirements for a Quality Program<sup>8</sup>

### 3. Terminology

#### 3.1 Definitions of Terms Specific to This Standard:

3.1.1 *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 1382°F (750°C).

3.1.2 *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 0.1875 in. (4.76 mm) in thickness and under 24 in. (610 mm) wide.

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

4.3 *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.

4.4 *Bar*—Rounds or flats from  $\frac{3}{16}$  in. (4.76 mm) to 4 in. (101.60 mm) in diameter or thickness. (Other sizes and shapes by special order.)

4.5 *Wire*—Rounds or flats less than  $\frac{3}{16}$  in. (4.76 mm) in diameter or thickness.

### 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,

5.1.3 Form (strip, sheet, plate, bar, or wire),

5.1.4 Condition (see 3 and 6.1),

<sup>1</sup> 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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<sup>2</sup> The boldface numbers in parentheses refer to the list of references at the end of the text.

<sup>3</sup> *Annual Book of ASTM Standards*, Vol 03.01.

<sup>4</sup> *Annual Book of ASTM Standards*, Vol 03.05.

<sup>5</sup> *Annual Book of ASTM Standards*, Vol 03.06.

<sup>6</sup> *Annual Book of ASTM Standards*, Vol 13.01.

<sup>7</sup> Available from the American Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.

<sup>8</sup> Available from the American Society for Quality, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

- 5.1.5 Mechanical Properties (if applicable for special conditions),
- 5.1.6 Finish (see 6.2),
- 5.1.7 Applicable dimension including size, thickness, width, or drawing number,
- 5.1.8 Special tests, if any, and
- 5.1.9 Special requirements.

**6. Materials and Manufacture**

6.1 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 alloy is usually multiple melted in arc furnaces (including furnaces such as plasma arc and electron beam) of a type conventionally used for reactive metals.

6.2 *Finish*—The mill product may be furnished to the implant manufacturer as descaled or pickled, sandblasted, chemically milled, ground, machined, peeled, polished, or combinations of these operations.

**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.

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 manufacturer shall not ship material that is outside the limits specified in Table 1. The product analysis tolerances shall conform to the check tolerances in Table 2.

7.2.1 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.

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

7.3 For referee purposes, use Test Methods E 120, E 1409, and E 1447 or other analytical methods agreed upon between the purchaser and the supplier.

7.4 Ensure that the 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 elements such as oxygen, nitrogen,

**TABLE 2 Product Analysis Tolerances<sup>A</sup>**

Element	Tolerance Under the Minimum or Over the Maximum Limit <sup>B</sup> , %, (mass/mass)
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.0020
Iron	0.10
Oxygen	0.02
Molybdenum	0.25

<sup>A</sup>Refer to AMS 2249.

<sup>B</sup>Under the minimum limit not applicable for elements where only a maximum percentage is indicated.

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 E 8. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in./minute (mm/mm/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 *Number of Tests*—Perform a minimum of two tension tests from each lot. A lot is defined as the total number of mill products produced under the same conditions at essentially the same time. Should either of the two test specimens not meet the specified requirements, test two additional test pieces representative of the same lot in the same manner. The lot will be considered in compliance only if both additional test pieces meet the specified requirements. If a specimen fails outside the gage, the test is null in accordance with Test Methods E 8, and a retest shall be performed.

**9. Special Requirements**

9.1 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.

9.2 The grain size in the annealed condition shall be 5 or finer, based upon Test Methods E 112.

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

9.4 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 when examined at 100× magnification.

**10. Certification**

10.1 The supplier’s certification that the material was manufactured in accordance with this specification together with a report of the test results shall be furnished to the implant manufacturer at the time of shipment.

**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
Molybdenum	14.00-16.00
Titanium <sup>A</sup>	balance

<sup>A</sup>The percentage of titanium is determined by difference and need not be determined or certified.