Standard Specification for
Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)\(^1\)

This standard is issued under the fixed designation F 136; 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 annealed titanium-6aluminum-4vanadium ELI (extra low interstitial) alloy (R56401) to be used in the manufacture of surgical implants.

1.2 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

2. **Referenced Documents**

2.1 **ASTM Standards:**

- E 8/E 8M Test Methods for Tension Testing of Metallic Materials
- E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
- E 290 Test Methods for Bend Testing of Material for Ductility
- E 539 Test Method for X-Ray Fluorescence Spectrometric Analysis of 6Al-4V Titanium Alloy
- E 1409 Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique
- E 1941 Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys
- E 2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry
- F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

2.2 **ISO Standards:**

- ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature
- ISO 9001 Quality Management Systems Requirements

2.3 **ASQ Standard:**

- ASQ C1 Specifications of General Requirements for a Quality Control Program\(^4\)

2.4 **Aerospace Material Specifications:**

- AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys\(^5\)

3. **Terminology**

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

3.1.1 **beta transus**, \(n\)—the minimum temperature at which the alpha plus beta phase can transform to 100% beta phase.

3.1.2 **lot**, \(n\)—the total number of mill products produced from one heat under the same conditions at essentially the same time.

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 10 in. (254 mm) wide and over, with widths greater than five times thickness. Plate up to 4.00 in. (101.60 mm), thick inclusive is covered by this specification.

4.4 **Bar**—Round bars and flats from 0.1875 in. (4.76 mm) to 4.00 in. (101.60 mm) in diameter or thickness (other sizes and shapes by special order).

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**—Rounds, flats, or other shapes less than 0.1875 in. (4.76 mm) in diameter.

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\(^1\) 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.

\(^2\) 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.


\(^5\) 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.*
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 ASTM designation and date of issue,
5.1.3 Form (sheet, strip, plate, bar, forging bar, or wire),
5.1.4 Condition (See Section 3 and 6.3),
5.1.5 Mechanical properties (if applicable, for special conditions),
5.1.6 Finish (See 6.2),
5.1.7 Applicable dimensions including size, thickness, width, length, or drawing number,
5.1.8 Special tests, if any, and
5.1.9 Other 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 mechanically descaled or pickled, abrasively 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 grinding if the resultant area meets the dimensional and surface finish requirements of this specification.

6.3 Condition—Material shall be furnished in the annealed or cold-worked condition. Mechanical properties for conditions other than those listed in Table 1 and Table 2 may be established by agreement between the supplier and the purchaser.

7. Chemical Requirements

7.1 The heat analysis shall conform to the chemical composition specified in Table 3. Ingot analysis may be used for reporting all chemical requirements, except hydrogen. Samples for hydrogen shall be taken from the finished mill product. The supplier shall not ship material with chemistry outside the requirements specified in Table 3.

7.2 Product 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 product analysis tolerances shall conform to the product tolerances in Table 4.

7.2.2 The product analysis is either for the purpose of verifying the composition of a heat or manufacturing lot or determining 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 analysis. Product analysis outside the tolerance limits allowed in Table 4 is cause for rejection of the product. A referee analysis may be used if agreed upon by the supplier and purchaser.

7.2.4 For referee purposes, use Test Methods E 539, E 1409, E 1447, E 1941, and E 2371 or other analytical methods agreed upon between the purchaser and the supplier.

7.3 Samples for chemical analysis shall be 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, 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 1 and Table 2.

8.2 Specimens for tension tests shall be machined and tested in accordance with Test Methods E 8/E 8M. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in./min (mm/mm/min) through yield and then the crosshead speed may be increased so as to produce fracture in approximately one additional minute.

8.2.1 Bar, Forging Bar, Shapes, and Wire—Test according to Test Methods E 8/E 8M. Should any test specimen not meet

### Table 1: Annealed Mechanical Properties of Bar, Wire, and Forgings

<table>
<thead>
<tr>
<th>Nominal Diameter or Distance Between Parallel Sides, in. (mm)</th>
<th>Tensile Strength min, psi (MPa)</th>
<th>Yield Strength (0.2 % offset) min, psi (MPA)</th>
<th>Elongation(^a) in 4D or 4W min, %</th>
<th>Reduction of Area(^b) min, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 0.187 (4.75) thickness or diameter</td>
<td>125 000 (860)</td>
<td>115 000 (795)</td>
<td>L</td>
<td>LT</td>
</tr>
<tr>
<td>0.187 (4.75) to under 1.75 (44.45), incl</td>
<td>125 000 (860)</td>
<td>115 000 (795)</td>
<td>10</td>
<td>...</td>
</tr>
<tr>
<td>1.75 (44.45) to under 2.50 (63.50), incl</td>
<td>120 000 (825)</td>
<td>110 000 (760)</td>
<td>8</td>
<td>...</td>
</tr>
<tr>
<td>2.50 (63.50) to 4.00 (101.60), incl</td>
<td>120 000 (825)</td>
<td>110 000 (760)</td>
<td>8</td>
<td>8%</td>
</tr>
</tbody>
</table>

\(^a\) E elongation of material 0.063 in. (1.6 mm) or greater in diameter (D) or width (W) shall be measured using a gage length of 2 in. or 4 D or 4 W. The gage length must be reported with the test results. The method for determining elongation of material under 0.063 in. (1.6 mm) in diameter or thickness may be negotiated. Alternatively, a gage 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 area.)

\(^b\) Applies to bar and forgings only. L = longitudinal; LT = long transverse; ST = short transverse. For round bar, the long and short transverse are identical tests, therefore only one transverse is required.

\(^c\) Transverse requirements in Table 1 apply only to product from which a tensile specimen not less than 2.50 in. (63.5 mm) in length can be obtained.
The percentage of titanium is determined by difference and need not be shown in Table 2. The bend test is applicable to sheet and strip products. The bend test is applicable to sheet and strip products. The bend test is applicable to sheet and strip products.

8.2.2 Tensile tests results for which any specimen fractures outside the gage length shall be considered acceptable, if both the elongation and reduction of area meet the minimum requirements specified. Refer to subsections 7.11.4 and 7.12.5 of Test Methods E 8/E 8M. 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.

8.3 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 bent portion. The bend shall be made around a mandrel which has a diameter equal to that shown in Table 2. Test conditions shall conform to Test Method E 290.

8.3.1 Sheet, Strip, and Plate—Test according to Test Methods E 8/E 8M. 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 8.0 in. (200 mm) in length for sheet and 2.50 in. (64.3 mm) in length for plate can be taken. Should any of these test specimens 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 will be considered in compliance only if all additional test pieces meet the specified requirements.

9. Special Requirements

9.1 The microstructure shall be a fine dispersion of the alpha and beta phases resulting from processing in the alpha plus beta field. There shall be no continuous alpha network at prior beta grain boundaries. There shall be no coarse, elongated alpha platelets.

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

9.3 Alpha case is not permitted for products supplied with a machined, ground, or chemically milled surface finish. For other products, there shall be no continuous layer of alpha case greater than 0.001 in. when examined at 100× magnification.

10. Significance of Numerical Limits

10.1 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 E 29.

11. Certification

11.1 The supplier shall provide a certification that the material was tested in accordance with this specification. A report of the test results shall be furnished to the purchaser at the time of shipment.

12. Quality Program Requirements

12.1 The producer shall maintain a quality program as defined in ASQ C1, ISO 9001, or similar quality program.

13. Keywords

13.1 metals (for surgical implants); orthopedic 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, physical, mechanical, and metallurgical properties of wrought annealed titanium-6aluminum-4vanadium ELI (extra low interstitial) alloy to be used in the manufacture of surgical implants.

X1.2 The microstructural requirements contained in this specification represent the current general consensus of opinion 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.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has 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 this alloy, it has been used as a control material in Practice F 981.

X2.2 No known surgical implant material has ever been shown to be completely free from adverse reactions in the human body. Long-term clinical experience of the use of the material 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.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F 136 – 02a) that may impact the use of this standard. (Approved Nov. 1, 2008.)

(1) Section 2, Referenced Documents, was updated.
(2) Section 6 and subsections 6.1, 6.2, and 6.3 were updated.
(3) Test Methods E 539, E 1941, and E 2371 were added to 7.2.4.
(4) Section 8.4 was deleted, and relevant information was moved to subsections 8.2 and 8.3.
(5) Mechanical Properties have been split into Table 1 for Bar, Wire, and Forgings and Table 2 for Sheet, Strip, and Plate.

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