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AMERICAN SOCIETY FOR TESTING AND MATERIALS
100 Barr Harbor Dr., West Conshohocken, PA 19428
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Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401) for Surgical Implant Applications[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-6 Aluminum-4 Vanadium 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 the standard. The metric equivalents in parentheses are provided for information only.

1.3 *This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

E 8 Test Methods of Tension Testing of Metallic Materials[2]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[3]

E 290 Test Method for Semi-Guided Bend Test for Ductility of Metallic Materials[2]

E 527 Practice for Numbering Metals and Alloys (UNS)[4]

E 1409 Test Methods for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique[3]

E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method[5]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone.[6]

2.2 *ASQ Standard:*

C1 Specifications of General Requirements for a Quality Control Program[7]

2.3 *Aerospace Material Specifications:*[8]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 4930 Titanium Alloy Bars, Forgings, and Rings 6AL-4V Extra Low Interstitial Annealed

2.4 *Society of Automotive Engineers Standard:*

SAE J1086 Practice for Numbering Metals and Alloys (UNS)[9]

3. Product Classification

3.1 *Strip*—Any product under 0.1875 in. (4.75 mm) in thickness and under 24 in. (610 mm) wide.

3.2 *Sheet*—Any product under 0.1875 in. (4.75 mm) in thickness and 24 in. (610 mm) or more in width.

3.3 *Plate*—Any product 0.1875 in. (4.75 mm) thick and over and 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.

3.4 *Bar*—Round bars and flats from 0.1875 in. (4.75 mm) to 4.00 in. (101.60 mm) in diameter or thickness (other sizes and shapes by special order).

3.5 *Forging bar*—Bar as described in 3.4, used for production of forgings, may be furnished in the hot rolled condition.

3.6 *Wire*—Rounds less than 0.1875 in. (4.75 mm) in diameter.

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 Applicable ASTM designation,

4.1.3 Form (sheet, strip, plate, wire, bar, or forging),

4.1.4 Condition (See 5.1),

4.1.5 Mechanical properties (if applicable, for special conditions),

4.1.6 Finish (See 5.2),

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

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

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

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

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

[7] Available from American Society for Quality, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

[8] Available from SAE, 400 Commonwealth Drive, Warrendale, PA 15096.

[9] New designation established in accordance with E527 and SAE J1086.

4.1.7 Applicable dimensions including size, thickness, width, or print number,

4.1.8 Special tests, and

4.1.9 Special requirements.

5. Materials and Manufacture

5.1 The various titanium mill products covered in this specification are normally formed with the conventional forging and rolling equipment found in primary ferrous and nonferrous plants. The ingot metal for such mill operations is usually melted in arc furnaces of a type conventionally used for reactive metals.

5.2 *Finish*—Annealed material may be furnished to the implant manufacturer as descaled or pickled, sandblasted, machined, ground, or combinations of these operations.

6. Chemical Requirements

6.1 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.

6.1.1 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.

6.2 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variation between laboratories in the measurement of chemical content. The manufacturer shall not ship material that is outside the limits specified in Table 1. Product analysis limits shall be as specified in Table 2.

6.3 For referee purposes, Methods E 120, E 1409, and E 1447 shall be used.

6.4 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. Therefore, in cutting samples for analysis, the operation should be carried out insofar as possible in a dust-free atmosphere. Chips should be clean and sharp. Samples for analysis should be stored in suitable containers.

7. Mechanical Requirements

7.1 Material supplied under this specification shall conform to the mechanical property requirements given in Table 3.

7.2 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. min (metric equivalent mm/mm/min) through the specified yield strength, and then the crosshead speed shall be increased so as to produce fracture in approximately one additional minute.

7.3 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 on a diameter equal to that shown in Table 3. Test conditions shall conform to Test Method E 290.

TABLE 1 Chemical Requirements

Element	Composition, %
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max	0.012[A]
Iron, max	0.25
Oxygen, max	0.13
Aluminum	5.5–6.50
Vanadium	3.5–4.5
Titanium[B]	balance

[A] Material 0.032 in. (0.813 mm) and under may have hydrogen content up to 0.0150 %.

[B] The percentage of titanium is determined by difference and need not be determined or certified.

TABLE 2 Product Analysis Tolerance[A]

Element	Tolerance Under the Minimum or Over the Maximum Limit (Composition %)[B]
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.0020
Iron	0.10
Oxygen	0.02
Aluminum	0.40
Vanadium	0.15

[A] Refer to AMS 2249.

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

8. Special Requirements

8.1 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.

8.2 The beta transus temperature for each heat shall be measured by a suitable method and reported on the materials certification.

8.3 Products supplied with a machined or ground surface finish shall have no alpha case. For other products, there shall be no continuous layer of alpha case when examined at 100×.

9. Quality Program Requirements

9.1 The producer shall maintain a quality program, such as, for example, is defined in Specifications C 1.

9.2 The manufacturer of surgical implants or medical applicances shall be assured of and may audit the producer's quality program for conformance to the intent of Specifications C 1, or other recognized program.

10. Certification

10.1 A certification shall be provided by the manufacturer of the material that the material was manufactured and tested in accordance with this specification. A report of test results shall be furnished at the time of shipment.

11. Keywords

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