



Designation: F1108 – 14

# Standard Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)<sup>1</sup>

This standard is issued under the fixed designation F1108; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

## 1. Scope\*

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for cast titanium-6aluminum-4vanadium alloy (UNS R56406).

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 may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance with the standard.

## 2. Referenced Documents

### 2.1 ASTM Standards:<sup>2</sup>

**B600** Guide for Descaling and Cleaning Titanium and Titanium Alloy Surfaces

**E3**

**E8** Test Methods for Tension Testing of Metallic Materials

**E120** Test Methods for Chemical Analysis of Titanium and Titanium Alloys (Withdrawn 2003)<sup>3</sup>

**E165** Practice for Liquid Penetrant Examination for General Industry

**E407** Practice for Microetching Metals and Alloys

**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 Titanium and Titanium Alloys by Inert Gas Fusion Thermal Conductivity/Infrared Detection Method

**F136** Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

**F601** Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

**F629** Practice for Radiography of Cast Metallic Surgical Implants

**IEEE/ASTM SI 10** American National Standard for Use of the International System of Units (SI): The Modern Metric System

2.2 *ISO Standard*:<sup>4</sup>

**ISO 6892** Metallic Materials—Tensile Testing at Ambient Temperature

**ISO 9001** Quality management systems -- Requirements

**ISO 13485** Medical devices -- Quality management systems -- Requirements for regulatory purposes

2.3 *Aerospace Material Specification*:<sup>5</sup>

**AMS 2249** Chemical Check Analysis Limits, Titanium and Titanium Alloys

2.4 *American Society for Quality Standard*:<sup>6</sup>

**ASQ C1** Specification of General Requirements for a Quality Control Program

2.5 *Society of Automotive Engineers*:<sup>5</sup>

**SAE J1086** Practice for Numbering Metals and Alloys (UNS)

## 3. Ordering Information

3.1 Inquiries and orders for material under this specification shall include the following information:

- 3.1.1 Quantity,
- 3.1.2 ASTM designation and issue date,
- 3.1.3 Applicable dimensions or drawing number,
- 3.1.4 Condition (see 4.1 and 4.2),
- 3.1.5 Finish (see 4.4 and 4.5),
- 3.1.6 Special tests (see Section 8),
- 3.1.7 Other requirements.

## 4. Materials and Manufacture

4.1 Castings conforming to this specification shall be produced by vacuum investment casting.

<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> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

<sup>3</sup> The last approved version of this historical standard is referenced on [www.astm.org](http://www.astm.org).

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

<sup>5</sup> Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, <http://www.sae.org>.

<sup>6</sup> Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

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

4.2 Castings covered by this specification shall be in the annealed and hot isostatically pressed condition.

NOTE 1—While hot isostatic processing (HIP) may enhance mechanical properties of Ti6Al-4V castings, it has also been shown to reduce the scatter in mechanical properties and therefore increases the confidence in reliability of castings.

4.3 Surface defects may be repaired by welding.

4.3.1 Weld repair shall be carefully executed as per written procedures by individuals qualified to perform those procedures.

4.3.2 ELI weld rod conforming to Specification **F136** shall be used where filler metal is needed.

4.3.3 Weld repairs shall be performed prior to final thermal processing.

NOTE 2—Under certain circumstances, a weld repair will act as a stress riser. Therefore, care should be exercised in the location and extent of weld repair as it relates to regions of the implant where significant stresses might be incurred.

4.4 All alpha case shall be removed by suitable means such as chemical milling or machining prior to HIP processing.

4.5 Parts shall be furnished in the descaled and cleaned condition in accordance with Guide **B600**.

4.6 Other thermal processes that meet the specific needs of the purchaser may be mutually agreed upon by the supplier and purchaser.

## 5. Chemical Composition

5.1 Product castings shall conform to the requirements prescribed in **Table 1**. The supplier shall not ship material outside the limits of **Table 1**. Chemical analysis shall be performed on a representative specimen cast from each heat using the same general procedures used in casting implants.

5.1.1 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.

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

**TABLE 1 Chemical Requirements**

Element	Composition, % (mass/mass)
Nitrogen	0.05 max
Carbon	0.10 max
Hydrogen	0.015 max
Iron	0.30 max
Oxygen	0.20 max
Aluminum	5.5 to 6.75
Vanadium	3.5 to 4.5
Titanium	Balance <sup>A</sup>

<sup>A</sup> The percentage of titanium is determined by difference and need not be determined or certified. Residual metallic element tolerance levels will be agreed upon between supplier and purchaser.

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

Element	Tolerance Under the Minimum or Over the Maximum Limit % (mass/mass) <sup>B</sup>
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.0030
Iron	0.08
Oxygen	0.04
Aluminum	0.40
Vanadium	0.15

<sup>A</sup> See AMS 2249.

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

5.2.1 The product analysis 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.

5.2.2 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product analysis.

5.3 For referee purposes, use Test Methods **E120**, **E1409**, and **E1447** or other analytical methods agreed upon between the purchaser and the supplier.

5.4 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, 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.

## 6. Mechanical Requirements

6.1 Material supplied under this specification shall conform to the mechanical property requirements prescribed in **Table 3**.

6.2 Specimens for tension tests shall conform to the mechanical property requirements prescribed in **Table 3**.

6.3 Specimens for tension tests shall be machined and tested in accordance with the methods in Test Methods **E8**. 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.

**TABLE 3 Mechanical Requirements<sup>A</sup>**

Tensile Strength, min, psi (MPa)	Yield Strength, (0.2% offset), min, psi (MPa)	Elongation <sup>B</sup> min, %	Reduction of Area min, %
125 000 (860)	110 000 (758)	8	14

<sup>A</sup> In the cast, HIP, and annealed condition.

<sup>B</sup> 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 4D or 4W. 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. Alternately, a gage length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser. (5.65 square root  $S_o$ , where  $S_o$  is the original cross sectional area.)