Designation: F1108 – 21

Standard Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)[1]

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 (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 cast titanium-6aluminum-4vanadium alloy (UNS R56406).

1.2 *Units*—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 the 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:*[2]

B600 Guide for Descaling and Cleaning Titanium and Titanium Alloy Surfaces

E3 Guide for Preparation of Metallographic Specimens

E8/E8M Test Methods for Tension Testing of Metallic Materials

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E407 Practice for Microetching Metals and Alloys

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

E2994 Test Method for Analysis of Titanium and Titanium Alloys by Spark Atomic Emission Spectrometry and Glow Discharge Atomic Emission Spectrometry (Performance-Based 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 Metric Practice

2.2 *ISO Standards:*[3]

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:*[4]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

2.4 *Society of Automotive Engineers:*[4]

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,

[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] 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.

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

[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**

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 10), and
3.1.7 Other requirements.

4. Materials and Manufacture

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

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

NOTE 1—While hot isostatic processing (HIP) may enhance mechanical properties of Ti6A1-4V 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. Weld repair may also impact metallurgical properties in the heat-affected zone, and care should be taken.

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.

5.1.2 Commercial metals may contain small amounts of elements other than those which are specified. It is generally 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 the reporting of an analysis for that element shall not be a basis for rejection unless previously agreed to between purchaser and supplier. Intentional elemental additions other than those specified in Table 1 are not permitted.

5.1.3 Analysis for elements not listed in Table 1 is not required to verify compliance with this specification.

5.2 *Product Analysis:*

5.2.1 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations between laboratories in the measurement of chemical content. The 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.

5.2.2 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.

5.2.3 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 2 are cause for rejection of the product. A referee analysis may be used if agreed upon by supplier and purchaser.

5.3 For referee purposes, use Test Methods E539, E1409, E1447, and E2994 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.

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[A]
Other elements (each)	0.10 max
Other elements (total)	0.40 max

[A] 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[A]

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

[A] See AMS 2249.
[B] Under the minimum limit not applicable for elements where only a maximum percentage is indicated.

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/E8M. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 mm/mm/min [in./in./min] through yield and then the crosshead speed may be increased so as to produce fracture in approximately one additional minute.

6.4 Mechanical test specimens shall be produced by the same general procedures used in casting surgical implants and shall be tested in accordance with Test Methods E8/E8M which may have a cast, ground, or machined finish on the reduced section. Alternatively, test specimens may be machined from surgical implant castings.

6.5 *Number of Tests*—Perform a minimum of two tension tests from each master heat. Should either of the two test specimens not meet the specified requirements, test two additional test pieces representative of the same master heat in the same manner. The lot will be considered in compliance only if both additional test pieces meet the specified requirements.

6.6 Tension test 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 Test Methods E8/E8M, subsections 7.11.4 and 7.11.5. 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.

7. Hot Isostatic Pressing

7.1 Hot isostatic pressing (HIP) is required for all medical grade implant castings produced to this specification.

7.2 Process castings under inert atmosphere at not less than 100 MPa [14 500 psi] within the range of 880 °C to 970 °C [1616 °F to 1778 °F], hold at selected temperature for 2 h minimum, and cool under inert atmosphere to below 425 °C [797 °F].

8. Thermal Processing

8.1 Heat treatment shall be as agreed between purchaser and supplier.

TABLE 3 Mechanical Requirements[A]

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

[A] In the cast, HIP, and annealed condition.

[B] Elongation of material 1.575 mm [0.062 in.] or greater in diameter (D) or width (W) shall be measured using a gage length of 2 in. or 4D or 4W minimum. The gage length shall be reported with the test results. The method for determining elongation of material under 1.575 mm [0.062 in.] in diameter or thickness may be negotiated. Alternatively, a gage length corresponding to ISO 6892 (5.65 times the square root of So, where So is the original cross-sectional area) may be used when agreed upon between the supplier and purchaser.

9. Microstructure

9.1 Alpha case is not permitted on finished castings when examined on a metallurgical cross section at 100× magnification.

9.2 The microstructural requirements and frequency of examinations shall be mutually agreed upon between the supplier and purchaser. Specimen preparation shall be in accordance with Guide E3 and Practice E407.

10. Nondestructive Examination

10.1 *Fluorescent Penetrant Examination*—Each individual part, when required by the purchaser, shall be subject to fluorescent penetrant examination in accordance with Practice F601. Unless otherwise specified, the castings shall be in the sandblasted condition before penetrant inspection. The acceptance criteria shall be agreed upon between the supplier and purchaser.

10.2 *Radiographic Examination*—Each individual part, when required by the purchaser, shall be subject to radiographic examination in accordance with Practice F629. Acceptance criteria to be mutually agreed upon between the supplier and purchaser.

11. Dimensions and Permissible Variation

11.1 *Units of Measure:*

11.1.1 *Selection*—This specification requires that the purchaser selects the units of measure (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

11.1.1.1 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

11.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's purchase order, specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification.

11.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.

11.1.2 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A of IEEE/ASTM SI 10 provides conversion tables and Annex B of IEEE/ASTM SI 10 provides rules for conversion and significant digits.

12. Significance of Numerical Limits

12.1 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 E29.