Designation: F1108 – 14

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 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:*[2]

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E120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys (Withdrawn 2003)[3]

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:*[4]

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:*[5]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

2.4 *American Society for Quality Standard:*[6]

ASQ C1 Specification of General Requirements for a Quality Control Program

2.5 *Society of Automotive Engineers:*[5]

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.

[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.

Current edition approved Nov. 1, 2014. Published January 2015. Originally approved in 1988. Last previous edition approved in 2009 as F1108 – 04 (2009). DOI: 10.1520/F1108-14.

[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] The last approved version of this historical standard is referenced on www.astm.org.

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

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

[6] 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 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.

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[A]

[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.

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[A]

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

[A] In the cast, HIP, and annealed condition.
[B] 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 So, where So is the original cross sectional area.)

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 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, sections 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. Microstructure

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

7.2 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.

8. Nondestructive Examination

8.1 *Fluorescent Penetrant Examination*—Each individual part 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.

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

8.3 Other additional methods of nondestructive inspection may be used as mutually agreed upon between the supplier and purchaser.

9. Dimensions and Permissible Variation

9.1 *Units of Measure:*

9.1.1 *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.

9.1.1.1 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.

9.1.1.2 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.

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

9.1.2 *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.

10. Certification

10.1 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.

11. Quality Program Requirements

11.1 The supplier shall maintain a quality program such as defined in ISO 9001, ISO 13485, or similar quality program.

12. Keywords

12.1 castings (for surgical implants); orthopaedic medical devices; titanium alloys; titanium alloys (for surgical implants)

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 This specification is intended to provide general guidelines for material requirements for Ti 6A1-4V castings for use in surgical implants. It is in no way intended to usurp the role of the design engineer in the development and manufacture of a functionally sound implant. For example, this specification does not preclude the use of ELI grade titanium; and the weld repair of defects. The engineer needs to be aware of the ramifications of such processing, though, on the safety and efficacy of the implant for its intended use.

X1.2 The UNS designation has been added for clarification, and a biocompatibility section has been added as an appendix.

X1.3 ISO Standards are listed for reference only. Although the ISO standards listed in Section 2 are similar to the corresponding ASTM standards, they may not identical. Use of an ISO standard, in addition to or instead of a preferred ASTM standard may be negotiated between the purchaser and supplier.

X2. BIOCOMPATIBILITY

X2.1 The material compositions covered by this specification have been employed successfully in human implant application in contact with soft tissue and bone for over a decade.

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. However, long term clinical experience has shown an acceptable level of biological response can be expected, if these materials are used in appropriate applications (**1**,**2**,**3**,**4**).[7]

[7] The boldface numbers in parentheses refer to the list of references at the end of this standard.

REFERENCES

(1) Laing, P. G., Ferguson, A. B., Jr., and Hodge, E. S., "Tissue Reaction in Rabbit Muscle Exposed to Metallic Implants," *Journal of Biomedical Materials Research*, Vol 1, 1967, pp 135–149.

(2) Laing, P. G., "Compatibility of Biomaterials," *Orthopedic Clinics of North America*, Vol 4, No. 2, April 1973, pp 249–273.

(3) Street, D. M., and Stevens, P. S., "A Humeral Replacement of Prosthesis for the Elbow," *Journal of Bone and Joint Surgery*, Vol 56A, No. 6, September 1974.

(4) Lynch, J. A., "Replacement Arthroplasty of the Elbow with Coonrad Total Elbow Prosthesis," *Orthopaedic Digest*, January 1976.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F1108 – 04(2009)) that may impact the use of this standard. (Approved Nov. 1, 2014)

(1) This specification was revised to add the latest template language approved at the May 2014 meeting of Subcommittee F04.12.