



Designation: F 1108 – 02

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

This standard is issued under the fixed designation F 1108; 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 inch-pound units are to be regarded as the standard. The SI equivalents of inch-pound units may be approximate.

2. Referenced Documents

2.1 ASTM Standards:

B 600 Guide for Descaling and Cleaning Titanium and Titanium Alloy Surfaces²

E 8 Test Methods for Tension Testing of Metallic Materials³

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys⁴

E 165 Test Method for Liquid Penetrant Examination⁵

E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique⁴

E 1447 Test Method for Determination Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method⁴

F 136 Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications⁶

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants⁶

F 629 Practice for Radiography of Cast Metallic Surgical Implants⁶

2.2 ISO Standard:

ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature⁷

2.3 Aerospace Material Specification:

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys⁸

2.4 American Society for Quality Standard:

ASQ C1 Specification of General Requirements for a Quality Control Program⁹

2.5 Society of Automotive Engineers:

SAE J1086 Practice for Numbering Metals and Alloys (UNS)⁸

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 7),

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 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 F 136 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

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 Apr. 10, 2002. Published June 2002. Originally published as F 1108 - 88. Last previous edition F 1108 - 97a.

² Annual Book of ASTM Standards, Vol 02.04.

³ Annual Book of ASTM Standards, Vol 03.01.

⁴ Annual Book of ASTM Standards, Vol 03.05.

⁵ Annual Book of ASTM Standards, Vol 03.03.

⁶ Annual Book of ASTM Standards, Vol 13.01.

⁷ Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York NY 10036.

⁸ Available from Society of Automotive Engineers, Inc., 400 Commonwealth Dr., Warrendale, PA 15096-0001.

⁹ Available from American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

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

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 B 600.

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.

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 E 120, E 1409, and E 1447 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

^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 E 8. 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.

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 E 8 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 the reduction of area meets the minimum requirements specified. If the reduction of area is less than the minimum requirement, discard the test and retest.

7. Nondestructive Examination

7.1 *Fluorescent Penetrant Examination*—Each individual part shall be subject to fluorescent penetrant examination in accordance with Test Method E 165 or Practice F 601, as appropriate for the surface condition of the casting being tested.

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 S_0 , where S_0 is the original cross sectional area.)

7.2 *Radiographic Examination*—Each individual part shall be subject to radiographic examination in accordance with Practice F 629. Acceptance criteria to be mutually agreed upon between supplier and purchaser.

7.3 Other additional methods of nondestructive inspection may be used as mutually agreed upon by supplier and purchaser.

8. Certification

8.1 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.

9. Quality Program Requirements

9.1 The supplier shall maintain a quality program as defined in ASQ C1.

10. Keywords

10.1 castings-surgical; orthopaedic medical devices-titanium/titanium alloy; titanium/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 6Al-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 be 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)**.¹⁰

¹⁰ 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 (F 1108 – 97a) that may impact the use of this standard.

- (1) This document was revised to be in line with the wording of newer documents using the standard template.
- (2) References to Specifications B 367 and B 381 were deleted.
- (3) ISO references were added for mechanical properties.
- (4) The revised wording for tensile specimens that break out of the gage length was added from Test Methods E 8.

ASTM International takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.

This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, at the address shown below.

This standard is copyrighted by ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959, United States. Individual reprints (single or multiple copies) of this standard may be obtained by contacting ASTM at the above address or at 610-832-9585 (phone), 610-832-9555 (fax), or service@astm.org (e-mail); or through the ASTM website (www.astm.org).