Designation: F 1108 – 97a

Standard Specification for Titanium-6 Aluminum-4 Vanadium 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 provides material requirements for titanium-6 aluminum-4 vanadium alloy castings 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 of inch-pound units may be approximate.

2. Referenced Documents

2.1 *ASTM Standards:*

B 367 Specification for Titanium and Titanium Alloy Castings[2]

B 381 Specification for Titanium and Titanium Alloy Forgings[2]

B 600 Practice for Descaling and Cleaning Titanium and Titanium Alloy Surfaces[2]

E 8 Test Methods of Tension Testing of Metallic Materials[3]

E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[4]

E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique[4]

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

F 136 Specification for Wrought Titanium 6A1-4V ELI Alloy for Surgical Implant Applications[6]

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[6]

F 629 Practice for Radiography of Cast Metallic Surgical Implants[6]

2.2 *ASQC Standard:*

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

3. Materials and Manufacture

3.1 Parts conforming to this specification shall be produced by vacuum investment casting.

3.2 Parts covered by this specification shall be an annealed condition in the hot isostatically pressed condition.

NOTE 1—While hot isostatic processing (HIP) may enhance mechanical properties of Ti6A14V castings, it has also been shown to reduce the scatter in mechanical properties and therefore increases the confidence in reliability of castings.

3.3 Surface defects may be repaired by welding.

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

3.3.2 ELI weld rod conforming to Specification F 136 shall be used where filler metal is needed.

3.3.3 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.

NOTE 3—While not covered by this specification, there are other thermal processes which meet specific needs of the implant manufacturer. These thermal treatments may be mutually agreed upon by the casting vendor and the implant manufacturer.

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

3.5 Parts shall be furnished in the descaled and cleaned condition in accordance with B 600.

4. Chemical Composition

4.1 The analysis for chemical composition of the castings shall conform to the requirements prescribed in Table 1. Chemical analysis shall be performed on a representative specimen cast from each heat using the same general procedures used in casting implants.

4.1.1 Requirements for the major and minor elemental constituents are listed in Table 1. Also listed are important

[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 April 10, 1997. Published March 1998. Originally published as F 1108 - 88. Last previous edition F 1108 - 97.

[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 03.06.

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

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

TABLE 1 Chemical Composition

Element	Composition, Weight %
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 remainder of the percent of titanium is determined by the difference. Residual metallic element tolerance levels will be agreed upon between producer and manufacturer.

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

4.2 Check analysis chemical requirements for samples taken from castings shall conform to the tolerances prescribed in Table 2.

4.2.1 *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 manufacturer shall not ship material that is outside the limits specified in Table 1.

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

NOTE 4—Use care in sampling titanium for chemical analysis because of its affinity for elements such as oxygen, nitrogen, and hydrogen. Therefore, in cutting samples for analysis, carry out the operation, insofar as possible, in a dust free atmosphere. Collect the sample from clean metal and use clean and sharp tools. Store samples for analysis in suitable containers.

5. Mechanical Requirements

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

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

5.3 Specimens for tension tests shall be machined and tested in accordance with the methods in Test Methods E 8 using a strain rate of 0.003 to 0.007 in./in. min. (mm/mm min.) through the specified yield range and then the crosshead speed shall be increased so as to produce fracture in approximately one additional minute.

TABLE 2 Product Analysis Tolerances

Nitrogen	0.02
Carbon	0.02
Hydrogen	0.0030
Iron	0.08
Oxygen	0.04
Aluminum	0.40
Vanadium	0.15

TABLE 3 Mechanical Requirements[A]

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

[A] In the cast, HIP, and annealed condition.
[B] Gage length = 4 × diameter.

5.4 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 ground finish on the reduced section. Alternatively, test specimens may be machined from surgical implant castings.

5.5 A minimum of two test specimens per heat shall be tested. If one specimen fails below the specified mechanical requirements or breaks outside the gage limits, two additional specimens shall be tested and both must pass.

6. Quality Program Requirements

6.1 The producer shall maintain a quality program such as, for example, is defined in ASQC C1, or equivalent.

6.2 The manufacturer of surgical implants or medical appliances shall be assured of and may audit the producer's quality program for conformance to the intent of ASQC C1 or other recognized program.

7. Nondestructive Examination

7.1 *Liquid Penetrant Examination*—Each individual part shall be subject to liquid penetrant examination in accordance with Practice F 601.

7.2 *Radiographic Examination*—Each individual part shall be subject to radiographic examination in accordance with Specification B 367, Section S1.

7.3 Other additional methods of nondestructive inspection may be used as mutually agreed upon by vendor and implant manufacturer.

8. Certification and Rejection

8.1 Certification and rejection shall be as specified in Specification B 367 and Specification B 381.

9. Packaging and Package Marking

9.1 Marking and packaging shall be as specified in Specification B 367 and Specification B 381.

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 Ti6A14V 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.

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**).[8]

[8] 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.