Designation: F 620 – ~~97~~00

~~An American National Standard~~

Standard Specification for ~~Titanium-6 Aluminum-4 Vanadium ELI~~ Alpha Plus Beta Titanium Alloy Forgings for Surgical ~~Implants [UNS R56401]~~ Implants [1]

This standard is issued under the fixed designation F 620; 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 requirements for ~~titanium-6 aluminum-4 vanadium ELI (extra low interstitial)~~ alpha plus beta titanium alloy forgings for surgical implants when the material forged conforms to Specifications F136 (UNS R56401), F1295 (UNS R56700), or F1472 (UNS R56400).

1.2 The values stated in inch-pound units are to be regarded as the standard.

2. Referenced Documents

2.1 *ASTM Standards:*

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[1] This specification is under the jurisdiction of ASTM Committee ~~F-4~~ F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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E 8 Test Methods for Tension Testing of Metallic Materials[2]
E 10 Test Method for Brinell Hardness of Metallic Materials[2]
E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[2]
E 92 Test Method for Vickers Hardness of Metallic Materials[2]
E 120 Test Methods for Chemical Analysis of Titanium and Titanium Alloys[3]
E 165 Test Method for Liquid Penetrant Examination[4]
E 1409 Test Method for Determination of Oxygen in Titanium and Titanium Alloys by the Inert Gas Fusion Technique[3]
E 1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by the Inert Gas Fusion Thermal Conductivity Method[5]
F 136 Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy (R56401) for Surgical Implant Applications[6]
F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[6]
F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[7]
F 1295 Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications [UNS R56700][6]
F 1472 Specification for Wrought Ti-6 Al-4V Alloy for Surgical Implant Applications[6]

2.2 *ASQC Standard:*
Cl Specifications of General Requirements for a Quality Program[7]

3. Ordering Information

3.1 Inquiries and orders for forgings under this specification shall include the following information:
3.1.1 Quantity, number of pieces,
3.1.2 ASTM designation, material grade,
3.1.3 Condition,
3.1.4 Mechanical properties (other than those specified herein),
3.1.5 Finish,
3.1.6 Applicable dimensions or print number,
3.1.7 Special tests, if any, and
3.1.8 Special requirements, if any.

4. Materials and Manufacture

4.1 Material for forgings shall be bars or wire fabricated in accordance with Specification F 136, F 1295, or F 1472.

4.2 The material shall be forged by hammering, pressing, extruding, or upsetting and shall be processed, if practicable, so as to cause metal flow during the hot-working operation in the direction most favorable for resisting stresses encountered in service, as may be indicated to the fabricator by the ~~implant manufacturer.~~ purchaser.

4.3 Forgings shall be free of splits, scale, cracks, flaws, and other imperfections not consistent with good commercial practice (see Note 1). Offset or mismatch allowance, dependent upon part size and configuration, shall be within standard forging tolerances.

NOTE 1—Compliance to these requirements may be verified by Test Method E 165 or Practice F 601 or other suitable methods.

4.4 After all hot-working operations, the forgings shall receive an annealing treatment, consisting of heating the parts to an appropriate elevated temperature for a specified dwell time followed by ~~rapid~~ appropriate cooling to meet the applicable metallurgical requirements specified herein.

4.5 Optional identification marks, including the manufacturer's logo, material designation, heat code number, and impression number, may be placed upon each forging, the method and location of which shall be specified by the purchaser.

5. Chemical Composition

5.1 When specified by the ~~implant manufacturer,~~ purchaser, the chemical composition of either the ~~raw~~ forging bars or the completed forgings shall be determined and confirmed by the forger, and shall meet the product analysis limits of ~~Specification F 136.~~ the appropriate material specification.

5.1.1 Hydrogen content must be determined for the annealed forgings. Samples for hydrogen analysis shall be taken after descaling, pickling, or chem milling, if these operations are performed.

[2] *Annual Book of ASTM Standards*, Vol 03.01.
[3] *Annual Book of ASTM Standards*, Vol 03.05.
[4] *Annual Book of ASTM Standards*, Vol 03.03.
[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.

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

6. Mechanical Requirements

6.1 When specified by the implant manufacturer, the

6.1 The mechanical properties of forgings shall be tested by the forger and shall comply with the minimum mechanical properties as specified by the implant manufacturer.

6.2 If mechanical property testing is required, test in Specifications F 136, F 1295, or F 1472.

6.1.1 Test specimens shall be taken from a representative forging if possible, or from a specially representative forged test bar, only if the configuration does not lend itself to yielding the required specimen. Any specially forged test bar must be annealed with the forgings it represents.

6.31.2 Testing shall be in accordance with 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.

6.42 When desired, Rockwell hardness may be specified on the implant manufacturer's purchase order or print drawing and shall be determined in accordance with Test Methods E 10, E 18,or E 92.

7. Special Requirements

7.1 The microstructure shall be a fine dispersion of the alpha- and beta phases resulting from processing in the temperature range of the alpha- plus beta phase field. There shall be no continuous alpha network at prior beta grain boundaries. There shall be no coarse, elongated alpha platelets. The alpha case, if present, shall be less than 0.020 in. (0.5 mm) in thickness.

8. Certification Requirements

8.1 The fabricator's forger's certification that the material was manufactured and tested in accordance with this specifica-tion, together with a report of the test results, shall be furnished to the implant manufacturer purchaser with each shipment.

9. Quality Program Requirements

9.1 The producer of material in accordance with this specification shall maintain a quality program as defined in ASQC Cl, or equivalent.

9.2 The manufacturer of surgical implants or medical appliances shall be assured of or may audit the material producer's quality program for conformance to the intent of ASQC C1, or equivalent.

10. Keywords

10.1 forgings—surgical implants; metals (for surgical implants)—titanium alloys; orthopaedic medical devices—titanium/titanium alloy; titanium/titanium alloys (for surgical implants)

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the chemical, mechanical, and metallurgical properties of wrought annealed Ti-6A1-4V ELI alpha plus beta titanium alloy forgings for surgical implants.

X1.2 The microstructural requirements contained in this specification represent the current general consensus with respect to optimization of mechanical properties for implant applications.

X1.3 The UNS designation has been added for clarification, title of the specification was changed to cover the alpha plus beta titanium alloy forgings and the Scope defines three specific compositions that have a B siomilar microstructures and mpechanical properties. The hydrogen content is now required to be determined in ty she final condition that the forgings will be shippen add to thed purchaser and mechanical properties are ndow requixred to be reported.

X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this specification has been employed successfully in human implant applications in contact with soft tissue and bone for over a ~~decade. Due to the well characterized level of local biological response established by this material, it has been used as a control material in Practice F 981.~~ 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 the material is used in appropriate applications.