



Standard Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition¹

This standard is issued under the fixed designation F620; 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 alloy forgings for surgical implants, in the alpha plus beta condition, when the material forged conforms to Specifications **F136** (UNS R56401), **F1295** (UNS R56700), **F1472** (UNS R56400), or **F2066** (UNS R58150).

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 non-conformance with the standard.

2. Referenced Documents

2.1 ASTM Standards:²

- E8/E8M** Test Methods for Tension Testing of Metallic Materials
- E10** Test Method for Brinell Hardness of Metallic Materials
- E18** Test Methods for Rockwell Hardness of Metallic Materials
- E29** Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
- E92** Test Method for Vickers Hardness of Metallic Materials (Withdrawn 2010)³
- E165** Practice for Liquid Penetrant Examination for General Industry
- 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

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

E2371 Test Method for Analysis of Titanium and Titanium Alloys by Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry (Performance-Based Test Methodology)

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

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

F1295 Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700)

F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)

F2066 Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150)

SI 10 American National Standard for the Use of the International System of Units (SI): The Modern Metric System

2.2 ISO Standard:

ISO 9001 Quality Management Systems⁴

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *lot*—the total number of forgings produced from the same heat under the same conditions and heat treated at essentially the same time.

4. Ordering Information

4.1 Inquiries and orders for forgings under this specification shall include the following information:

- 4.1.1 Quantity, number of pieces,
- 4.1.2 ASTM designation and date of issue, material grade,
- 4.1.3 Condition,
- 4.1.4 Mechanical properties,

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

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

- 4.1.5 Finish,
- 4.1.6 Applicable dimensions or drawing number,
- 4.1.7 Special tests, if any, and
- 4.1.8 Other requirements.

5. Materials and Manufacture

5.1 Material for forgings shall be bars or wire fabricated in accordance with Specification **F136**, **F1295**, **F1472**, or **F2066**.

5.2 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 purchaser.

5.3 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 **E165** or Practice **F601** or other suitable methods.

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

5.5 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.

6. Chemical Composition

6.1 When specified by the purchaser, the chemical composition of either the forging bars or the completed forgings shall be determined and confirmed by the forger, and shall meet the product analysis limits of the appropriate material specification.

6.1.1 Hydrogen content shall be determined on annealed forgings. Samples for hydrogen analysis shall be taken after descaling, pickling, or chemical milling, if these operations are performed.

6.2 For referee purposes, Test Methods **E1409**, **E1447**, and **E2371** shall be used.

7. Mechanical Requirements

7.1 The mechanical properties of forgings shall be tested by the forger and shall comply with the minimum mechanical properties as specified in Specifications **F136**, **F1295**, **F1472**, or **F2066**.

7.1.1 Test specimens shall be taken from a representative forging if possible, or from a representative forged test bar. A representative test bar may only be used if the configuration is such that a test bar cannot be obtained. Any specially forged test bar must be annealed with the forgings it represents.

7.1.2 Specimens for tension tests shall be machined and tested in accordance with 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.

7.2 Number of Tests:

7.2.1 Perform at least one tension test from each lot in the longitudinal direction. Should any test specimen not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test specimen. The lot will be considered in compliance only if all additional test pieces meet the specified requirements.

7.2.2 Tensile tests results for which any specimen fractures outside the gauge length shall be considered valid, if both the elongation and reduction of area meet the minimum requirements specified. If either the elongation or reduction of area is less than the minimum requirement, invalidate the specimen and retest. Retest one specimen for each invalidated specimen.

7.2.3 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.

7.3 When desired, hardness may be specified on the purchase order or drawing and shall be determined in accordance with Test Methods **E10**, **E18**, or **E92**.

8. Microstructure

8.1 The microstructure shall be a fine dispersion of the alpha and beta phases resulting from processing in 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. Alpha case, if present, shall be less than 0.5 mm [0.020 in.] in thickness.

9. Significance of Numerical Limits

9.1 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**.

10. Dimensions and Permissible Variations

10.1 Units of Measure:

10.1.1 *Selection*—This specification requires that the purchaser selects the units (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.

10.1.1.1 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.

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

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

10.1.2 *Conversion of Units*—If the supplier’s test equipment does not normally 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. ASTM **SI 10** provides guidelines for the use of SI units. Annex A provides conversion tables and Annex B provides rules for conversion and significant digits

11. Certification Requirements

11.1 The supplier shall provide a certification that the material was tested in accordance with this specification and met all requirements. A report of the test results shall be furnished to the purchaser at the time of shipment.

11.2 Gauge length must be reported with elongation.

12. Quality Program Requirements

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

13. Keywords

13.1 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 titanium alloy forgings in the alpha plus beta condition for surgical implants.

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

X2. BIOCOMPATIBILITY

X2.1 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. The alloy compositions covered by this specification, however, have been subjected to testing in laboratory animals, and have been used clinically for more than a decade. The

results of these studies indicate a well-characterized level of local biological response that is equal to or less than that produced by the reference material unalloyed titanium (see Specification **F67**) that has a long history of successful clinical application in soft tissue and bone implants in humans.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F620 – 06) that may impact the use of this standard. (Approved Dec. 1, 2011.)


(1) Modified the title, scope, and **X1.1** to indicate that these are titanium forgings in the alpha plus beta condition, rather than Alpha-Beta alloys produced as forgings.

(2) Specification **F2066** (UNS R58150) was added as an applicable material.

(3) Dimensions and Permissible Variations section was added.

(4) Changed “Special Requirements” to “Microstructure.”

(5) Deleted former subsection X1.3.

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