



Designation: ~~F621 – 12~~ **F621 – 12 (Reapproved 2017)**

Standard Specification for Stainless Steel Forgings for Surgical Implants¹

This standard is issued under the fixed designation F621; 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 of forged stainless steel for surgical implants when the material forged conforms to Specifications **F138** (UNS S31673), **F1314** (UNS S21910), **F1586** (UNS S31675), **F2229** (UNS S29108), or **F2581** (UNS R56320).

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.

1.3 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

2. Referenced Documents

2.1 ASTM Standards:²

A262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels

A473 Specification for Stainless Steel Forgings

E8 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 Methods for Vickers Hardness and Knoop Hardness of Metallic Materials

E112 Test Methods for Determining Average Grain Size

E165 Practice for Liquid Penetrant Examination for General Industry

E353 Test Methods for Chemical Analysis of Stainless, Heat-Resisting, Maraging, and Other Similar Chromium-Nickel-Iron Alloys

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

F1314 Specification for Wrought Nitrogen Strengthened 22 Chromium-13 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)

F1586 Specification for Wrought Nitrogen Strengthened 21Chromium-10Nickel-3Manganese-2.5Molybdenum Stainless Steel Alloy Bar for Surgical Implants (UNS S31675)

F2229 Specification for Wrought, Nitrogen Strengthened 23Manganese-21Chromium-1Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29108)

F2581 Specification for Wrought Nitrogen Strengthened 11Manganese-17Chromium-3Molybdenum Low-Nickel Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S29225)

IEEE/ASTM SI 10 American National Standard for Metric Practice

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 Oct. 1, 2012; May 1, 2017. Published October 2012; June 2017. Originally approved in 1979. Last previous edition approved in 2008 as ~~F621 – 08~~ F621 – 12. DOI: 10.1520/F0621-12.10.1520/F0621-12R17.

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.

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

2.2 ISO Standards:³

ISO 5832-1 Implants for Surgery—Metallic Materials Part 1: Wrought Stainless Steel

ISO 5832-9 Implants for Surgery—Metallic Materials Part 9: Wrought High Nitrogen Stainless Steel

ISO 9001 Quality Managements Systems—Requirements

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 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,

4.1.2 ASTM designation and date of issue,

4.1.3 ASTM material (alloy) standard and date of issue,

4.1.4 Condition,

4.1.5 Mechanical properties,

4.1.6 Finish,

4.1.7 Applicable dimensions or drawing number,

4.1.8 Special tests (if any), and

4.1.9 Other special requirements.

5. General Requirements for Delivery

5.1 Material furnished to this specification shall conform to the applicable requirements in the current edition of Specification **A473**.

5.2 In the case where a conflict exists between this specification and that listed in **5.1**, this specification shall take precedence.

6. Materials and Manufacture

6.1 Material for forgings shall be bars or wire fabricated in accordance with Specifications **F138**, **F1314**, **F1586**, **F2229**, or **F2581**, generally in the unannealed condition with a finish suitable for forging.

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

6.3 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 if not specified on the part drawing.

NOTE 1—Compliance to these requirements may be verified by Practices **E165** or **F601** or other suitable methods.

6.4 After all hot-working operations, the forgings shall receive an annealing treatment, when necessary, by heating the parts to an appropriate elevated temperature for a specified dwell time followed by rapid cooling to meet the applicable metallurgical requirements specified by the purchaser.

6.5 Heat treating the alloys specified in Specifications **F2229** and **F2581** in an oxidizing atmosphere results in the formation of a magnetic (ferritic) surface layer on the heat-treated product. This surface layer shall be removed from the finished product prior to its use as a medical or surgical device. To avoid this effect during processing, heating cycles shall be kept as short as possible.

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

7. Chemical Composition

7.1 The stainless steel forgings shall conform to the chemical requirements prescribed in the applicable alloy specification: **F138**, **F1314**, **F1586**, **F2229**, or **F2581**, as applicable.

7.2 For referee purposes, Test Methods **E353** shall be used.

8. Mechanical Requirements

8.1 The mechanical properties of forgings shall be tested by the forger and shall comply with the minimum mechanical properties as specified in Specifications **F138**, **F1314**, **F1586**, **F2229**, or **F2581**, as applicable.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.