



Designation: F621 – 12 (Reapproved 2021)^{ε1}

Standard Specification for Stainless Steel Forgings for Surgical Implants¹

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^{ε1} NOTE—X2.2 was updated editorially in August 2021.

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 are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems shall not be combined.

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/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

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.

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 Testing 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

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

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 Specification **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 Practice **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 Specification **F138**, **F1314**, **F1586**, **F2229**, or **F2581**, as applicable.

8.1.1 Test specimens shall be taken from a representative forging if possible. 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 shall be in the same condition as the forgings it represents.

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

8.3 The mechanical properties shall be determined in accordance with Test Methods **E8/E8M**.

8.4 *Number of Tests:*

8.4.1 Perform at least one tension test from each lot in the longitudinal direction, or as indicated on the part drawing. Should this test result not meet the specified requirements, test two additional test pieces representative of the same lot, in the same manner, for each failed test piece. The lot shall be considered in compliance only if both additional test pieces meet the specified requirements.

8.4.2 Tensile tests results for which any specimen fractures outside the gage length shall be considered acceptable if both the elongation and reduction of area meet the minimum requirements specified. Refer to Test Methods **E8/E8M**, sections 7.11.4 and 7.12.5.

8.4.2.1 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.

9. Special Tests

9.1 *Corrosion Tests*—Forgings furnished to this specification shall be capable of passing the test for intergranular corrosion susceptibility in accordance with Practice E of Practices **A262**.

9.2 *Grain Size*—On the cross section examined, the grain size shall be predominately ASTM No. 4 or finer. No regions exhibiting grain size larger than ASTM No. 3 shall be allowed. Test procedures shall be in accordance with Test Methods **E112**.