

Designation: F 621 – 02

Standard Specification for Stainless Steel Forgings for Surgical Implants¹

This standard is issued under the fixed designation F 621; 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 Specification F 138 (UNS S31673), Specification F 1314 (UNS S21910), or Specification F 1586 (UNS S31675).

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

2. Referenced Documents

2.1 ASTM Standards:

- A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels²
- A 473 Specification for Stainless Steel Forgings²
- E 8 Test Methods for Tension Testing of Metallic Materials³
- E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials³
- E 112 Test Methods for Determining Average Grain Size³
- E 165 Practice for Liquid Penetrant Examination⁴
- E 353 Test Methods for Chemical Analysis of Stainless, Heat-Resisting, Maraging, and Other Similar Chromium-Nickel-Iron Alloys⁵
- F 138 Specification for Wrought-18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)⁶
- F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants⁶
- F 1314 Specification for Wrought Nitrogen Strengthened-22Chromium-13Nickel-5Manganese-2.5Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S21910)⁶
- F 1586 Specification for Wrought Nitrogen Strengthened–21Chromium-10Nickel-3Manganese-2.5Molybdenum Stainless Steel Alloy Bar for Surgical Implants (UNS S31675)⁶

2.2 ISO Standards:⁷

- 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
- 2.3 American Society for Quality Standard:
- Cl Specifications of General Requirements for a Quality Control Program⁸

3. Ordering Information

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

- 3.1.1 Quantity,
- 3.1.2 ASTM designation and date of issue,
- 3.1.3 ASTM material (alloy) standard and date of issue,
- 3.1.4 Condition,
- 3.1.5 Mechanical properties,
- 3.1.6 Finish, Chiedal
- 3.1.7 Applicable dimensions or drawing number,
- 3.1.8 Special tests, if any, and
- 3.1.9 Other special requirements.

4. General Requirements for Delivery

4.1 Material furnished to this specification shall conform to the applicable requirements in the current edition of Specification A 473.

4.2 In the case where a conflict exists between this specification and that listed in 4.1, this specification shall take precedence.

5. Materials and Manufacture

5.1 Material for forgings shall be bars or wire fabricated in accordance with Specifications F 138, F 1314, or F 1586, generally in the unannealed condition with a finish suitable for forging.

5.2 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

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 Apr. 10, 2002. Published June 2002. Originally published as F 621 - 79. Last previous edition F 621 - 97.

² Annual Book of ASTM Standards, Vol 01.03.

³ Annual Book of ASTM Standards, Vol 03.01.

⁴ Annual Book of ASTM Standards, Vol 03.03.

⁵ Annual Book of ASTM Standards, Vol 03.05.

⁶ Annual Book of ASTM Standards, Vol 13.01.

 $^{^7\,\}rm{Available}$ from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

⁸ Available from American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.