Designation: F 621 – 97

Standard Specification for Stainless Steel Forgings for Surgical Implants[1]

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 F 138 (R31673), F 1314 (S21910), or F 1586.

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 Steels[2]

A 370 Test Methods and Definitions for Mechanical Testing of Steel Products[2]

A 473 Specification for Stainless and Heat-Resisting Steel Forgings[3]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[4]

E 112 Test Methods for Determining Average Grain Size[4]

E 165 Practice for Liquid Penetrant Inspection Method[5]

E 353 Test Methods for Chemical Analysis of Stainless, Heat-Resisting, Maraging, and Other Similar Chromium-Nickel-Iron Alloys[6]

F 138 Specification for Stainless Steel Bars and Wire for Surgical Implants (Special Quality)[7]

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[7]

F 1314 Specification for Wrought Nitrogen Strengthened-22 Chromium-12.5 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants[7]

F 1586 Specification for Wrought Nitrogen Strengthened–21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants[7]

2.2 *ASQC Standard:*

Cl Specifications of General Requirements for a Quality Control Program[8]

3. Ordering Information

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

3.1.1 Quality; 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, and

3.1.8 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 Specification 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 in the direction most favorable for resisting stresses encountered in service, as may be indicated to the fabricator by the implant manufacturer.

5.3 Forgings shall be free of splits, scale, cracks, inequalities, 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 Practices E 165 or F 601 or other suitable methods.

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

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[2] *Annual Book of ASTM Standards*, Vol 01.03.

[3] *Annual Book of ASTM Standards*, Vol 01.05.

[4] *Annual Book of ASTM Standards*, Vol 03.01.

[5] *Annual Book of ASTM Standards*, Vol 03.03.

[6] *Annual Book of ASTM Standards*, Vol 03.05.

[7] *Annual Book of ASTM Standards*, Vol 13.01.

[8] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

5.4 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 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 as specified by the purchaser.

6. Chemical Composition

6.1 When specified by the implant manufacturer, the chemical compositions 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 138, F 1314, or F 1586.

6.2 For referee purposes, Test Methods E 353 shall be used.

7. Mechanical Properties

7.1 The mechanical properties of stainless steel forgings produced from the three alloys of concern in this specification depend on a number of factors, including the specific alloy from which the forgings are produced and the fabrication practice. Different combinations of specific alloy and fabrication practice will provide substantially different mechanical properties.

7.2 When specified by the implant manufacturer, 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.

7.3 If tension testing is required, test specimens should be taken from a representative forging, if possible, or from a specially forged test bar only if the configuration does not lend itself to yielding the required specimen.

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

7.5 The mechanical properties shall be determined in accordance with Test Methods A 370.

8. Special Requirements

8.1 *Corrosion Tests*— Forgings furnished to this specification shall be capable of passing the test for intergranular corrosion susceptibility in accordance with the current edition of Practices A 262, Practice E.

8.2 *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 E 112.

8.3 Other special requirements shall be as specified on the purchase order or print.

9. Certification

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

10. Quality Program Requirements

10.1 The producer of material in accordance with this specification shall maintain a quality program as defined in ASQC C1 or equivalent.

10.2 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.

11. Keywords

11.1 forgings—surgical implants; metals (for surgical implants)—stainless steel; stainless steel—surgical applications

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the chemical, mechanical, and metallurgical properties of wrought stainless steel 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 This specification has been expanded to cover forgings of three specific alloys; each UNS designation has been included for clarification. A Biocompatibility section has been added as an appendix.

X2. BIOCOMPATIBILITY

X2.1 The material compositions covered by this standard have been employed successfully in human implant applications in contact with soft tissue and bone for over a 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 these materials are used in appropriate applications.