Designation: F621 – 12

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

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.

## 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E92 Test Method for Vickers Hardness of Metallic Materials (Withdrawn 2010)[3]

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

2.2 *ISO Standards:*[4]

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,

[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.

[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**

4.1.3 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.

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 Methods E10, E18, or E92.

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

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, 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.

9.3 Fluorescent penetrant inspection shall be performed on forgings. Penetrant inspections shall be performed in accordance with Practices E165 or F601.

9.4 Other special requirements shall be as specified by the purchaser.

## 10. Dimensions and Permissable 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 (PO), 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 the purchaser and supplier.

10.1.2 *Conversion of Units*—If the supplier's test equipment does not 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. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A of that standard provides conversion tables and Annex B provides rules for conversion and significance.

## 11. Significance of Numerical Limits

11.1 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.

## 12. Certification

12.1 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.

## 13. Quality Program Requirements

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

## 14. Keywords

14.1 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.

X1.4 ISO standards are listed for reference only. Although the ISO standards listed in 2.2 are similar to the corresponding ASTM standards, they may not be identical. Use of an ISO standard in addition to or instead of a preferred ASTM standard may be negotiated between purchaser and supplier. In this specification, the composition of ISO 5832-1 is similar to ASTM Specification F138 and the composition of ISO 5832-9 is similar to ASTM Specification F1586.

X1.5 *Units of Measure*:

X1.5.1 *ASTM Policy*—ASTM is promoting the use of rationalized SI (metric) units in their standards. The F12.04 Committee has modified this specification to facilitate the transition by the medical materials industry to SI between now and 2018. In the first phase of this transition, running to 2013, the specifications will be structured to allow the use of either SI or inch-pound units. The choice of primary units in each specification will be determined by the industry using the specification. The change to SI units during this period may be initiated by the purchaser through his purchase documentation. In the second phase of this transition, the specifications shall be written with SI as the primary units. Harmonization with corresponding ISO documents should be considered when assigning the SI values.

## X2. BIOCOMPATIBILITY

X2.1 The material compositions covered by this specification 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.

## SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F621 – 08) that may impact the use of this standard. (Approved Oct. 1, 2012.)

*(1)* Editorial corrections have been made in order to meet terminology and formatting guidelines established for implant material standards in Subcommittee F04.12.
*(2)* Former wording in 1.2 was replaced with wording allowing independent SI and inch-pound units.
*(3)* Section 2.1, ASTM Standards, added IEEE/ASTM SI 10, American National Standard for Metric Practice.
*(4)* Former subsection 2.3, ASQ C1 Specification of General Requirements for a Quality Program and former footnote 5 were deleted.
*(5)* Section 10, Dimensions and Permissible Variations, was added to allow selection of units to be certified.
*(6)* Section 12, Certification, was updated.
*(7)* Reference to ASQ C1 quality program was deleted from Section 13, Quality Program Requirements.
*(8)* Appendix subsection X1.5 was added to support the use of SI units.
*(9)* Summary of Changes was updated.