



Designation: F 961 – 03

Standard Specification for 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Forgings for Surgical Implants (UNS R30035)¹

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1. Scope

1.1 This specification covers the requirements for 35cobalt-35nickel-20chromium-10molybdenum alloy (UNS R30035) forgings for surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard. The SI equivalents in parentheses are for information only.

2. Referenced Documents

2.1 ASTM Standards:

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products²

E 8 Test Methods for Tension Testing of Metallic Materials³

E 10 Test Method for Brinell Hardness of Metallic Materials³

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials³

E 92 Test Method for Vickers Hardness of Metallic Materials³

E 112 Test Methods for Determining Average Grain Size³

E 140 Hardness Conversion Tables for Metals Relationship Among Brinell Hardness, Vickers Hardness, Rockwell Hardness, Superficial Hardness, Knoop Hardness, and Scleroscope Hardness³

F 562 Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)⁴

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants⁴

F 688 Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035)⁴

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone⁴

2.2 ISO Standard:

ISO 5832-6 Implants for Surgery—Metallic Materials—Part 6: Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy⁵

2.3 American Society for Quality Control Standard:

ASQ C1 Specification of General Requirements for a Quality Program⁶

3. Ordering Information

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

3.1.1 Quantity (weight or number of pieces),

3.1.2 ASTM designation and date of issue,

3.1.3 Mechanical properties (if applicable, for other requirements),

3.1.4 Form,

3.1.5 Applicable dimensions, including size, thickness, width, and length (exact, random, multiples), or drawing number,

3.1.6 Condition,

3.1.7 Finish,

3.1.8 Special tests (if any), and

3.1.9 Other requirements.

4. Materials and Manufacture

4.1 Material for forgings shall be bars, plate, sheet, or wire manufactured in accordance with Specification F 562 or Specification F 688. The material shall be generally in the solution-annealed condition with a finish suitable for forging.

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

4.3 Forgings shall be free of splits, scale, cracks, inequalities, flaws, and other imperfections not consistent with good commercial practice.

NOTE 1—Compliance to these requirements may be verified by Practice

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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 13.01.

⁵ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

⁶ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.



F 601 or other suitable method.

4.4 When specified by the purchaser, a thermal treatment shall be performed, as specified, after all forging operations are performed.

4.5 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 identification shall be as specified by the purchaser.

5. Chemical Composition

5.1 The heat analysis shall conform to the chemical composition requirements prescribed in Specification F 562, Table 1.

5.2 The chemical composition of samples taken for product analysis shall conform to Specification F 562, Table 2.

5.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods A 751.

6. Mechanical Requirements

6.1 The mechanical properties of as-forged or annealed forgings shall meet the minimum mechanical properties as specified in Specification F 562.

6.2 Test specimens shall be taken from a representative forging, if possible, or from a representative forged test bar, only if the configuration does not lend itself to yielding the required specimen. Any special forged test bar must be annealed with the forging it represents.

6.3 When desired, Rockwell hardness may be specified on the purchaser's purchase order or engineering drawing. Rockwell hardness shall be determined in accordance with Test Methods E 18.

NOTE 2—When desired, Brinell hardness may be taken as described in Test Method E 10 or Vickers hardness may be taken as described in Test Method E 92 and converted to Rockwell hardness in accordance with Hardness Conversion Tables E 140.

6.4 Specimens for tension tests shall be machined and tested in accordance with Test Method E 8. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in./min (mm/mm/min) through the yield strength, and then the cross-head speed may be increased so as to produce fracture in approximately one additional minute.

7. Special Tests

7.1 The grain size shall be agreed upon between the purchaser and the supplier and shall be tested in accordance with Test Methods E 112.

7.2 Other special requirements shall be as specified on the purchase order or engineering drawing.

8. Certification

8.1 Certification shall be provided by the supplier reporting that the forgings meet the requirements of the purchaser. A report of the test results shall be furnished at the time of each shipment.

9. Quality Program Requirements

9.1 The supplier shall maintain a quality program, such as that defined in Specification ASQ C1.

10. Keywords

10.1 cobalt alloys (for surgical implants); cobalt-nickel-chromium-molybdenum alloys; forgings; surgical implants; metals (for surgical implants)

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize composition and properties to ensure consistency in 35cobalt-35nickel-20chromium-10molybdenum alloy forgings used in the manufacturing of medical devices.

X1.2 ISO standards are listed for reference only. Use of an ISO standard in addition to or instead of a preferred ASTM standard may be negotiated between purchaser and supplier.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has been employed successfully in human implant applications (1-6)⁷ in contact with soft tissue and bone since 1974. Due to the well-characterized level of biological response exhibited by

this alloy, it has been used as a control material in Practice F 981.

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 the material is used in appropriate applications.

⁷ The boldface numbers in parentheses refer to the list of references at the end of this standard.