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

This standard is issued under the fixed designation F 961; 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 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.~~

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

1.2 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

2. Referenced Documents

2.1 ~~ASTM Standards:~~²

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

E 8 Test Methods for Tension Testing of Metallic Materials

E 10 Test Method for Brinell Hardness of Metallic Materials

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

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E 92 Test Method for Vickers Hardness of Metallic Materials

E 112 Test Methods for Determining Average Grain Size

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

E 165 Test Method for Liquid Penetrant Examination

E 354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys

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

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

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

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

2.2 ~~ISO Standard:~~ ISO Standards:³

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

ISO 9001 Quality Management Systems—Requirements

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*, Vol 01-03, volume information, refer to the standard's Document Summary page on the ASTM website.

³ *Annual Book of ASTM Standards*, Vol 03.01.

³ 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.

2.3 *American Society for Quality Control Standard.*⁴
 ASQ C1 Specification of General Requirements for a Quality Program

3. ~~Ordering Information~~

~~3. 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. Terminology~~

~~3.1 Definitions of Terms Specific to This Standard:~~

- ~~3.1.1 lot, n—the total number of forgings produced from the same heat under the same conditions at essentially the same time.~~

4. ~~Materials and Manufacture~~

~~4.1 Material for forgings shall be bars, plate, sheet, or wire manufactured in accordance with Specification F562 or Specification F688~~

~~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 Mechanical properties (if applicable, for special conditions),~~
- ~~4.1.4 Form,~~
- ~~4.1.5 Applicable dimensions, including size, thickness, width, and length (exact, random, or multiples), or drawing number,~~
- ~~4.1.6 Condition,~~
- ~~4.1.7 Finish,~~
- ~~4.1.8 Special tests (if any), and~~
- ~~4.1.9 Other requirements.~~

5. ~~Materials and Manufacture~~

~~5.1 Material for forgings shall be bars or wire fabricated 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.~~

~~5.2 The material shall be forged by hammering, pressing, 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 purchaser.~~

~~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 Test Method E 165 or Practice 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 F562, Table 1.~~

~~5.2 The chemical composition of samples taken for product analysis shall conform to Specification F562, Table 2.~~

⁴ Annual Book of ASTM Standards, Vol 13.01.

⁴ Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, <http://www.asq.org>.

~~5.3 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Test Methods A751.~~

~~5.4 After all hot-working operations have been completed, the forgings shall receive an annealing treatment consisting of heating the parts to an appropriate elevated temperature for a specified dwell time followed by appropriate 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. Mechanical Requirements

~~6.1 The mechanical properties of as-forged or annealed forgings shall meet the minimum mechanical properties as specified in Specification F562 Chemical Requirements~~

~~6.1 When specified by the purchaser, the chemical composition of either the forging bars or the completed forgings shall be determined and confirmed by the forger, and shall meet the product analysis limits of the appropriate material specification.~~

~~6.2 For referee purposes, Test Methods E 354 and A 751 shall be used.~~

7. Mechanical Requirements

7.1 Tensile Properties:

~~7.1.1 The mechanical properties of forgings shall be tested by the forger and shall comply with the minimum mechanical properties as specified in Specification F 562.~~

~~7.1.2 Test specimens shall be taken from a representative forging if possible, or from a representative forged test bar. 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 must be annealed with forgings it represents.~~

~~7.1.3 Specimens for tension tests shall be machined and tested in accordance with Test Methods E8.~~

7.2 Number of Tests:

~~7.2.1 Perform at least one tension test from each lot in the longitudinal direction. 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.~~

~~7.2.2 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 sections 7.11.4 and 7.12.5 of Test Methods E 8.~~

~~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 E18~~

~~7.2.3 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.~~

7.3 Hardness:

~~7.3.1 Hardness values shall be determined in accordance with Test Methods E 10 or Test Methods E 18.~~

~~7.3.2 When desired, hardness limits may be specified on the purchase order or drawing and shall be determined in accordance with Test Methods E 10 or 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 E8. 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 crosshead 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 E112~~

8. Special Tests

~~8.1 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.~~