



Designation: F961 – 20

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

This standard is issued under the fixed designation F961; 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 chemical, mechanical, and metallurgical requirements for 35cobalt-35nickel-20chromium-10molybdenum alloy (UNS R30035) in the form of forgings, used for the manufacture of surgical implants.

1.2 *Units*—The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems shall not be combined.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 ASTM Standards:²

- A484/A484M Specification for General Requirements for Stainless Steel Bars, Billets, and Forgings
- A555/A555M Specification for General Requirements for Stainless Steel Wire and Wire Rods
- A751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products
- E8/E8M Test Methods for Tension Testing of Metallic Materials

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.

- 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 Methods for Vickers Hardness and Knoop Hardness of Metallic Materials
 - E112 Test Methods for Determining Average Grain Size
 - E140 Hardness Conversion Tables for Metals Relationship Among Brinell Hardness, Vickers Hardness, Rockwell Hardness, Superficial Hardness, Knoop Hardness, Scleroscope Hardness, and Leeb Hardness
 - E165 Practice for Liquid Penetrant Testing for General Industry
 - E354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys
 - F562 Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)
 - F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants
 - F688 Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035)
 - IEEE/ASTM SI 10 American National Standard for Use of the International System of Units (SI): The Modern Metric System
- ### 2.2 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
 - ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

3. 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.

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

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;
- 4.1.3 Mechanical properties (if applicable, for special conditions);
- 4.1.4 Form (bar or wire);
- 4.1.5 Applicable dimensions, including size, thickness, width, and length (exact, random, or multiples), or drawing number;
- 4.1.6 *Tolerances*—Unless otherwise specified by purchaser, tolerances must meet the requirements of Specification [A484/A484M](#), Specification [A555/A555M](#), or both, as applicable;
- 4.1.7 Condition (see [5.1](#));
- 4.1.8 Finish;
- 4.1.9 Special tests (if any); and
- 4.1.10 Other requirements.

5. Materials and Manufacture

5.1 Condition:

5.1.1 Material for forgings shall be bars or wire fabricated in accordance with Specification [F562](#) or Specification [F688](#). The material shall be generally in the solution-annealed condition with a finish suitable for forging.

5.1.2 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.

5.2 Finish:

5.2.1 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 Practice [E165](#) or Practice [F601](#) or other suitable method.

5.2.2 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.

5.2.3 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 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 [E354](#) and [A751](#) 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 [F562](#).

7.1.2 Test specimens shall be taken from a representative forging if possible, or from a representative forged test bar. A representative forged 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 the forgings it represents.

7.1.3 Specimens for tension tests shall be machined and tested in accordance with Test Methods [E8/E8M](#).

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 test results for which any specimen fractures outside the gauge 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 7.11.5 of Test Methods [E8/E8M](#). 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 Method [E10](#) or Test Methods [E18](#).

7.3.2 When desired, hardness limits may be specified by the purchaser. Hardness determination shall be made on a product cross section, midway between the center and surface, if the cross section is adequate.

NOTE 2—When desired, Brinell hardness may be taken as described in Test Method [E10](#) or Vickers hardness may be taken as described in Test Methods [E92](#) and converted to Rockwell hardness in accordance with Hardness Conversion Tables [E140](#).

8. Dimensions and Permissible Variations

8.1 Units of Measure:

8.1.1 *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, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

8.1.1.1 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.

8.1.1.2 In the absence of historic precedence, if the units used to define the product on the purchaser's purchase order (PO), specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification.

8.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.