Designation: F961 – 14

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 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 may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance with the standard.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

A751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products

E8/E8M 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E92 Test Method for Vickers Hardness of Metallic Materials (Withdrawn 2010)[3]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

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 Examination 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)

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

IEEE/ASTM SI 10 American National Standard for Use of the International System of Units (SI): The Modern Metric System

2.2 *ISO Standards:*[4]

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

ISO 9001 Quality Management Systems—Requirements

2.3 *American Society for Quality Control Standard:*[5]

ASQ C1 Specification of General Requirements for a Quality Program

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.

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

Current edition approved Oct. 1, 2014. Published November 2014. Originally approved in 1985. Last previous edition approved in 2008 as F961 – 08. DOI: 10.1520/F0961-14.

[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.

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

***A Summary of Changes section appears at the end of this standard**

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 F562 or Specification F688. The material shall be generally in the solution-annealed condition with a finish suitable for forging.

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 E165 or Practice F601 or other suitable method.

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. 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 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/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 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 E8/E8M.
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 E10 or Test Methods E18.
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 E10 or E18.

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 Method E92 and converted to Rockwell hardness in accordance with Hardness Conversion Tables E140.

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 E112.

8.2 Any other special requirements shall be specified by the purchaser.

9. Dimensions and Permissible Variations

9.1 *Units of Measure:*
9.1.1 *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.
9.1.1.1 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.
9.1.1.2 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.
9.1.1.3 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.

9.2 *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 IEEE/ASTM SI 10 provides conversion tables and Annex B of IEEE/ASTM SI 10 provides rules for conversion and significance.

10. Significance of Numerical Limits

10.1 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.

11. Certification

11.1 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.

12. Quality Program Requirements

12.1 The supplier shall maintain a quality program such as that which is defined in Specification ASQ C1 or ISO 9001.

13. Keywords

13.1 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 the chemical, mechanical, and metallurgical properties of 35cobalt-35nickel-20chromium-10molybdenum alloy forgings for surgical implants.

X1.2 ISO standards are listed for reference only. Although the ISO 5832-6 listed in Section 2 is similar to the corresponding ASTM standard, they are not identical. Use of the ISO standard, in addition to or instead of the preferred ASTM standard may be agreed upon between the purchaser and supplier.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has been employed successfully in human implant applications **(1-6)**[6] in contact with soft tissue and bone for over a decade. Due to the well-characterized level of biological response exhibited by this alloy, it has been used as a control material in Practice F981.

X2.2 No known surgical implant material has ever been shown to be completely free of adverse reactions in the human body. Long-term clinical experience of the use of the material referred to in this specification, however, has shown an acceptable level of biological response can be expected, if the material is used in appropriate applications.

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

REFERENCES

(1) Willert, H. G., Buchhorn, U., Zichner, L., "Clinical Experience with Mueller Total Hip Endoprostheses of Different Design and Material," *Archives of Orthopaedic and Traumatic Surgery*, 97, 1980, pp. 197–205.

(2) Gaechter, A., Galante, G., "MP35N, A Corrosion Resistant High-Strength Alloy for Orthopaedic or Surgical Implants: Two Year Bioassay," *Journal of Biomedical Materials Research*, Vol 10, 1976, pp. 829–831.

(3) Escales, F., Galante, J., Rostoker, W., Coogan, P. S., "MP35N, A Corrosion Resistant High-Strength Alloy for Orthopaedic Surgical Implants: Bioassay Results," *Journal of Biomedical Materials Research*, Vol 9, No. 3, 1976, pp. 303–313.

(4) Kuehne, D., Willert, H. G., "The Tissue Compatibility of the Forging Alloy (Protasul 10) with the Hitherto Used Implant Alloys (Co-Cr-Mo Casting Alloy) and (AISI 316L) After an Implantation Period of One Year," Doctoral Thesis, Osteological Research Laboratory of Orthopaedic University, Frankfurt am Main/Frg, 1975.

(5) Bauman, R., Semlitsch, M., "Biological and Mechanical Behavior or Newly Developed Implant Materials in Animal Studies," Sulzer reprint, Re/28.09.00, 1974, pp. 1–9.

(6) ISO/TC-150/SC-1/WG-1, Swiss Standard Association, Group 129–Surgical Implants, Draft Report of WG-1, Swiss Proposal 056509, Part 2, Comments on Biocompatibility, Davos Meeting, June 1974.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F961 – 08) that may impact the use of this standard. (Approved Oct. 1, 2014.)

(1) Editorial changes have been made in order to meet the terminology and formatting guidelines that have been established for implant specifications.

(2) Section 9, Dimensions and Permissible Variations, was added.

(3) Language has been added to address the selection of units of measure for material certification.

(4) Section X1.3 was deleted.