Designation: F 961 – 96

Standard Specification for Cobalt-35 Nickel-20 Chromium-10 Molybdenum 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 cobalt-35 nickel-20 chromium-10 molybdenum alloy forgings for surgical implants.

1.2 The values stated in inch-pound units are to be regarded as the standard.

2. Referenced Documents

2.1 *ASTM Standards:*

A 751 Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products[2]

E 8 Test Methods for Tension Testing of Metallic Materials[3]

E 10 Test Method for Brinell Hardness of Metallic Materials[3]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[3]

E 112 Test Methods for Determining the Average Grain Size[3]

E 140 Hardness Conversion Tables for Metals[3]

E 165 Practice for Liquid Penetrant Examination[4]

F 562 Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications[5]

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[5]

F 688 Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants[5]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials in Muscle and Bone[5]

2.2 *Federal Standard:*

Federal Test Method No. 151 Metals; Test Methods[6]

2.3 *American Society for Quality Control Standard:*

Cl Specification of General Requirements for a Quality Program[7]

3. Terminology

3.1 *Definition of a Term Specific to This Standard:*

3.1.1 *capability*—the word "capability" is used to indicate the ability of cold-worked material to attain specific mechanical properties after thermal aging treatment.

4. Ordering Information

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

4.1.1 Quantity (weight or number of pieces),

4.1.2 ASTM designation and date of issue,

4.1.3 Form,

4.1.4 Condition,

4.1.5 Mechanical properties (if applicable),

4.1.6 Finish,

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

4.1.8 Special tests, and

4.1.9 Special requirements.

5. Materials and Manufacture

5.1 Material for forgings shall be bars, plate, sheet, 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.

5.2 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 fabricator by the implant manufacturer.

5.3 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 E 165 or Practice F 601 or other suitable methods.

5.4 When specified by the implant manufacturer, a thermal treatment shall be performed, as specified, after all forging

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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 03.03.

[5] *Annual Book of ASTM Standards*, Vol 13.01.

[6] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

[7] Available from American Society for Quality Control, 161 West Wisconsin Ave., Milwaukee, WI 53203.

operations are performed.

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 identification shall be as specified by the purchaser.

5.6 Forgings shall be supplied in the as-forged or forged-and-capability-aged condition, as specified by the implant manufacturer.

6. Chemical Composition

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

6.2 The chemical composition of samples taken for product analysis shall conform to the check tolerances prescribed in Specification F 562, Table 2.

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

7. Mechanical Requirements

7.1 When specified by the implant manufacturer, the mechanical properties of forgings shall be tested by the forger and shall comply with the minimum mechanical properties as specified by the implant manufacturer. Specification F 562, Section 7, shall be used as a guideline.

7.2 If tension testing is required, test specimens should be taken from a representative forging, if possible, or from a specially forged test bar only if the configuration does not lend itself to yielding the required specimen.

7.3 When desired, Rockwell hardness may be specified on the implant manufacturer's purchase order or print. 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 and converted to Rockwell hardness in accordance with Hardness Conversion Tables E140.

7.4 The mechanical properties shall be determined in accordance with Test Methods E 8 using a strain rate of 0.003 to 0.007 in./in. min. (mm/mm min.) through the specified yield range, and then the crosshead speed shall be increased so as to produce fracture in approximately one additional minute.

8. Special Tests

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

8.2 Other special requirements shall be as specified on the purchase order or print.

9. Certification

9.1 The fabricator's certification that the material was manufactured and tested in accordance with this specification, together with a report of the test results, shall be furnished to the implant manufacturer with each shipment.

10. Quality Program Requirements

10.1 The producer shall maintain a quality program, such as that defined in Specification ASQC C1.

10.2 The manufacturer of surgical implants or medical appliances shall be assured of the producer's quality program for conformance to the intent of Specification ASQC C1, or any other recognized program.

11. Keywords

11.1 cobalt alloys (for surgical implants); cobalt-nickels alloy; forgings; surgical implant; metals (for surgical implants)

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this specification is to characterize the composition and properties to assure consistency in the starting material used in the manufacture of medical devices.

X1.2 The acceptable metal conditions include as-forged or as-forged-and-capability aged, the choice dependent upon the medical device design and its intended application.

X1.3 The UNS designation has been added for clarification, and a Biocompatibility section has been added as an appendix.

X2. BIOCOMPATIBILITY

X2.1 The material composition covered by this specification has been employed successfully in human implant applications in contact with soft tissue and bone for over decade. Due to the well characterized level of local biological response established by this material, 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.

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.