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Standard Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)¹

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1. Scope*

- 1.1 This specification covers requirements of cobalt-28chromium-6molybdenum alloy (UNS R31537, R31538, R31539) high-strength forgings for the manufacture of surgical implants. The properties specified in this document specifically apply to finished or semifinished parts that receive no subsequent thermomechanical processing.
- 1.2 Wrought material to be used as forging stock in the manufacture of forgings conforming to this specification, typically hot worked and unannealed with a surface finish suitable for forging, shall be fabricated and supplied in accordance with F1537.
- 1.3 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 non-conformance with the standard.

2. Referenced Documents

2.1 ASTM Standards:²

E8 Test Methods for Tension Testing 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

E112 Test Methods for Determining Average Grain Size

E165 Practice for Liquid Penetrant Examination for General Industry

E930 Test Methods for Estimating the Largest Grain Observed in a Metallographic Section (ALA Grain Size)

F75 Specification for Cobalt-28 Chromium-6 Molybdenum

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.

Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

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

F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)

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 6892 Metallic Materials—Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems—Requirements

2.3 American Society for Quality Standard:⁴

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 of starting material under the same conditions at essentially the same time.

4. Ordering Information

- 4.1 Inquiries and orders for material under this specification shall include the following information:
 - 4.1.1 Quantity, number of pieces
 - 4.1.2 ASTM designation, date of issue, and alloy number,
 - 4.1.3 Condition,
 - 4.1.4 Mechanical properties,
 - 4.1.5 Finish.
 - 4.1.6 Applicable dimensions or drawing number,
 - 4.1.7 Special tests, if any, and
 - 4.1.8 Other requirements.

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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



5. Materials and Manufacture

- 5.1 Materials for forgings shall be bar, rod, or wire fabricated in accordance with Specification F1537.
- 5.2 The material shall be forged by hammering, pressing, rolling, extruding, or upsetting, and shall be processed, if practical, so as to cause metal flow during the hot-working operation to be in the most favorable direction for resisting stresses encountered in service, as may be indicated to the supplier by the purchaser.
- 5.3 Forgings shall be free of splits, scale, cracks, 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.
- 5.4 Optional indentification 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 which shall be as specified by the purchaser.

Note 1—Compliance to these requirements may be verified by Test Method E165 or Practice F601 or other suitable methods.

6. Chemical Requirements

6.1 The cobalt-28chromium-6molybdenum alloy forgings shall conform to the chemical requirements prescribed in Table 1 of Specification F1537. The supplier shall not ship material that is outside the limits specified in Table 1 of Specification F1537 for the applicable alloys. Specification F1537 contains three alloys:

Alloy 1 Low Carbon (UNS R31537)
Alloy 2 High Carbon (UNS R31538)
Alloy 3 Dispersion Strengthened (UNS R31539)

7. Mechanical Requirements

- 7.1 Tensile Properties: a/catalog/standards/sist/57
- 7.1.1 Tensile properties shall be determined in accordance with Test Methods E8.
- 7.1.2 The mechanical properties of test specimens prepared from finished or semifinished parts shall conform to the requirements in Table 1.
- 7.1.3 Tension test specimens shall be produced from finished or semifinished parts or from material having the same process history as that which exists in the final forging. Tension specimens may have a ground finish on the reduced section and may be taken in a direction parallel to the long axis of the finished or semifinished part.
- 7.1.4 A minimum of two tension test specimens shall be tested. Should either of the two specimens not meet the

specified requirements, two additional specimens shall be tested and both must pass.

- 7.1.5 If any fracture takes place outside the middle half of the gauge length or in a punched or scribed gauge mark within the reduced section, the elongation value obtained may not be representative of the material. In acceptance testing, if the elongation so measured meets the minimum requirements specified, no further testing is required, but if the elongation is less than the minimum requirements, discard the test and retest.
- 7.1.6 In some instances, mechanical test pieces may not be obtainable directly from forged parts due to their configuration or small size. Instead of mechanical testing, these parts shall exhibit hardness of HRC 35 to 45 when tested in accordance with Test Methods E18.
- 7.2 Hardness—Forgings conforming to this specification shall have a minimum Rockwell C hardness of 35 HRC. The hardness determination shall be performed in accordance with Test Methods E18.

8. Dimensions and Permissable 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 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.
- 8.1.2 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. ASTM SI 10 provides guidelines for the use of SI units. Annex A of that standard provides conversion tables and Annex B provides rules for conversion and significance.

TABLE 1 Mechanical Requirements

Ultimate Tensile Strength, min, psi, (MPa)	Yield Strength (0.2 % offset), min, psi (MPa)	Elongation, ⁴ in 2 in. or 4D or 4W, min %	Reduction in Area, min, %	Hardness, HRC, min
170 000 (1172)	120 000 (827)	12	12	35

^A Elongation of material 0.063 in. (1.6 mm) or greater in diameter (D) or width (W) shall be measured using a gauge length of 2 in. or 4D or 4W. The gauge length must be reported with the test results. The method for determining elongation of material under 0.063 in. (1.6 mm) in diameter or thickness may be negotiated. Alternately, a gauge length corresponding to ISO 6892 may be used when agreed upon between supplier and purchaser. (5.65 sqaure root So, where So is the original cross sectional area.)