



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

This standard is issued under the fixed designation F799; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

## 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*:<sup>2</sup>

- [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](#)

<sup>1</sup> 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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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto: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*:<sup>3</sup>

[ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature](#)

[ISO 9001 Quality Management Systems—Requirements](#)

2.3 *American Society for Quality Standard*:<sup>4</sup>

[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.

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

<sup>4</sup> 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

## 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 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 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:

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 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 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, <sup>A</sup> in 2 in. or 4D or 4W, min %	Reduction in Area, min, %	Hardness, HRC, min
170 000 (1172)	120 000 (827)	12	12	35

<sup>A</sup> 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 square root  $S_o$ , where  $S_o$  is the original cross sectional area.)

## 9. Special Tests

9.1 The average grain size of forgings shall be ASTM No. 5 or finer when tested in accordance with Test Methods E112. In forgings it may not be possible to fully recrystallize the entire microstructure to a fine grain size. Duplex microstructures exhibiting areas of unrecrystallized grains as large as ASTM No. 2 (or ALA No. 2, as applicable, see Test Method E930) shall be acceptable provided a minimum of 50 % of the area of each section examined displays an average grain size of ASTM No. 5 or finer; and the average microhardness of the larger grained regions is the equivalent of HRC 38 or greater. In quantities of 10 % (by area of the metallographic section in question) or less, unrecrystallized grains as large as ASTM No. 0 (or ALA No. 0, as applicable) shall be acceptable provided the average microhardness of the larger grained regions is the equivalent of HRC 40 or greater.

9.2 When specified by the purchaser, fluorescent penetrant inspection shall be performed on forgings. These penetrant inspections shall be performed in accordance with Practices E165 and F601.

## 10. Significance of Numerical Limits

10.1 The following applies to all specified limits in this specification. To determine conformance to these limits, an

observed 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 of conformance 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 alloy suppliers and any processors shall maintain a quality program as defined in ASQ C1 or ISO 9001.

## 13. Keywords

13.1 cobalt alloys; cobalt alloys (for surgical implants); cobalt-chromium-molybdenum; forgings; metals (for surgical implants)

## APPENDIXES

### (Nonmandatory Information)

#### X1. RATIONALE

X1.1 The purpose for this specification is to characterize composition and properties to assure consistency in thermomechanically processed cobalt-28chromium-6molybdenum forgings used in the manufacturing of medical devices that receive no subsequent metallurgical processing.

X1.2 Published data<sup>5,6</sup> indicate that material with a fine-grained homogeneous metallurgical structure resulting from forging will be superior with respect to tensile strength and fatigue resistance compared to material conforming to Specification F75. Based upon this, requirements include fine-grained microstructure and high tensile strength.

X1.3 Some complex metallic phases, such as carbides, oxides, or carbonitrides, or combinations thereof, may be present in the microstructure of this alloy.

X1.4 ISO standards are listed for reference only. Although the ISO standards listed in Section 2 are similar to the corresponding ASTM standards, they may not be identical. Use of an ISO standard in addition to or instead of a preferred ASTM standard may be negotiated between the purchaser and supplier.

#### X1.5 Units of Measure

X1.5.1 *ASTM Policy*—ASTM is promoting the use of rationalized SI (metric) units in their standards. The F12.04 Committee has modified this specification to facilitate the transition by the medical materials industry to SI between now and 2018. In the first phase of this transition, running to 2013, the specifications will be structured to allow the use of either SI or inch-pound units. The choice of primary units in each specification will be determined by the industry using the specification. The change to SI units during this period may be initiated by the purchaser through his purchase documentation. In the second phase of this transition the specifications will be written with SI as the primary units. Harmonization with corresponding ISO documents should be considered when assigning the SI values.

<sup>5</sup> Bardos, D. I., "High Strength Co-Cr-Mo Alloy for Prostheses," *Current Concepts of Internal Fixation of Fractures*, edited by H. Uthoff, Springer Verlag, New York, NY, 1980, p 111.

<sup>6</sup> Weisman, S., "Vitallium FHS Forged High-Strength Alloy," *Current Concepts of Internal Fixation of Fractures*, p 118.

## X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has been successfully employed in human implants for over a decade. This material has been found to produce a well-characterized level of local biological response when tested in accordance with Practice F981 or equivalent.

X2.2 The material composition conforming to this specification has been evaluated for biocompatibility and corrosion

resistance and has been found to be comparable to material conforming to Specification F75.

X2.3 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 this material is used in appropriate applications.

## SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F799 – 06) that may impact the use of this standard. (Approved June 1, 2011)

(1) Changed units of measure throughout the standard, so that SI and inch-pound units are both considered to be standard.

(2) Added Section 8 for Dimensions and Permissible Variations, regarding units of measure.

(3) Added X1.5 regarding units of measure.

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