Designation: F 799 – 02

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

This standard is issued under the fixed designation F 799; 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 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 The values stated in inch-pound units are to be regarded as the standard. The SI equivalents of the inch-pound units may be approximate.

1.3 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 F 1537.

2. Referenced Documents

2.1 *ASTM Standards:*

E 8 Test Methods for Tension Testing of Metallic Materials[2]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[2]

E 112 Test Methods for Determining Average Grain Size[2]

E 165 Test Method for Liquid Penetrant Examination[3]

E 930 Test Methods for Estimating the Largest Grain Observed in a Metallographic Section (ALA Grain Size)[2]

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[4]

F 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[4]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[4]

F 1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants[4]

2.2 *ISO Standards:*[5]

ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature

2.3 *American Society for Quality Standard:*[6]

ASQ C1 Specification of General Requirements for a Quality Program

3. Ordering Information

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

3.1.1 Quantity,

3.1.2 ASTM designation, date of issue, and alloy number,

3.1.3 Mechanical properties,

3.1.4 Form,

3.1.5 Applicable dimensions or drawing number,

3.1.6 Condition,

3.1.7 Special tests, if any, and

3.1.8 Other requirements.

4. Materials and Manufacture

4.1 Materials for forgings shall be bar, rod, or wire fabricated in accordance with Specification F 1537.

4.2 The material shall be forged by hammering, pressing, rolling, extruding, or upsetting, and shall be processed, if practicable, so as to cause metal flow 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.

4.3 Forgings shall be free of splits, scale, cracks, flaws, and other imperfections not consistent with good commercial practice.

4.4 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.

[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] *Annual Book of ASTM Standards*, Vol 03.01.

[3] *Annual Book of ASTM Standards*, Vol 03.03.

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

[5] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

[6] Available from American Society for Quality, 600 N. Plankinton Ave., Milwaukee, WI 53203.

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

5. Chemical Requirements

5.1 The cobalt-28chromium-6molybdenum alloy forgings shall conform to the chemical requirements prescribed in Table 1 of Specification F 1537. The supplier shall not ship material that is outside the limits specified in Table 1 of Specification F 1537 for the applicable alloys. Specification F 1537 contains three alloys:

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

6. Mechanical Requirements

6.1 *Tensile Properties*:

6.1.1 Tensile properties shall be determined in accordance with Test Methods E 8.

6.1.2 The mechanical properties of test specimens prepared from finished or semifinished parts shall conform to the requirements in Table 1.

6.2 *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 E 18.

7. Special Tests

7.1 The average grain size of forgings shall be ASTM No. 5 or finer when tested in accordance with Test Methods E 112. 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 E 930) 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.

TABLE 1 Mechanical Requirements

Ultimate Tensile Strength, min, psi, (MPa)	Yield Strength (0.2 % offset), min, psi (MPa)	Elongation,[A] 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 gage length of 2 in. or 4D or 4W. The gage 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 gage 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.)

6.1.3 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.

6.1.4 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.

6.1.5 If any fracture takes place outside the middle half of the gage length or in a punched or scribed gage 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.

6.1.6 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 E 18.

7.2 When specified by the purchaser, fluorescent penetrant inspection shall be performed on forgings. These penetrant inspections shall be performed in accordance with Practices E 165 and F 601.

8. Certification

8.1 The supplier'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 purchaser with each shipment.

9. Quality Program Requirements

9.1 The alloy suppliers and any processors shall maintain a quality program as defined in ASQ C1 or equivalent.

10. Keywords

10.1 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[7,8] 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 F 75. Based upon this, requirements include fine-grained microstructure and high tensile strength.

X1.3 The maximum iron content has been lowered to coincide with compositions that are commercially available.

X1.4 Some complex metallic phases, such as carbides, oxides, or carbonitrides, or combinations thereof, may be present in the microstructure of this alloy.

X1.5 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.

[7] Bardos, D. I., "High Strength Co-Cr-Mo Alloy for Prostheses," *Current Concepts of Internal Fixation of Fractures*, edited by H. Uhthoff, Springer Verlag, New York, NY, 1980, p 111.

[8] 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 F 981 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 F 75.

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

Committe F04 has identified the location of selected changes to this standard since the last issue (F 799 – 99) that may impact the use of this standard.

(*1*) The three alloys contained in F 1537 were added to the chemical requirements section.
(*2*) A footnote for elongation in Table 1 to clarify gage length of 2 in. with 4D or 4W was added, along with an ISO reference.
(*3*) Wording was revised in many areas to update the specification (editorial changes).