Designation: F799 – 19

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

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 (ε) indicates an editorial change since the last revision or reapproval.

1. Scope*

1.1 This specification covers requirements of cobalt-28 chromium-6 molybdenum 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 Specification F1537.

1.3 *Units*—The SI units in this standard are the primary units. The values stated in either primary SI units or secondary 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.

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E8/E8M 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/E165M Practice for Liquid Penetrant Testing 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 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 Insertion into Bone

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

IEEE/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 6892-1 Metallic materials – Tensile testing – Part 1: Method of test at room temperature

ISO 9001 Quality management systems – Requirements

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 Units to be certified (SI or inch-pound),

4.1.4 Condition,

[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.

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

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

4.1.5 Mechanical properties,
4.1.6 Finish,
4.1.7 Applicable dimensions or drawing number,
4.1.8 Special tests, if any, and
4.1.9 Other requirements.

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 with these requirements may be verified by Practice E165/E165M or Practice F601, or other suitable methods.

6. Chemical Requirements

6.1 The cobalt-28 chromium-6 molybdenum 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/E8M.

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 semi-finished 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 semi-finished 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 purchase order, 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. IEEE/ASTM SI 10 provides guidelines for the use

TABLE 1 Mechanical Requirements

Ultimate Tensile Strength, min, MPa (psi)	Yield Strength (0.2 % offset), min, MPa (psi)	Elongation,[A] in 50.8 mm (2 in.) or 4D or 4W, min, %	Reduction in Area, min, %	Hardness, HRC, min
1172 [170 000]	827 (120 000)	12	12	35

[A]Elongation of material 1.575 mm (0.062 in.) or greater in diameter (D) or width (W) shall be measured using a gage length of 50.8 mm (2 in.) or 4D or 4W. The gage length shall be reported with the test results. The method for determining elongation of material under 1.575 mm (0.062 in.) in diameter or thickness may be negotiated. Alternatively, a gage length corresponding to ISO 6892-1 (5.65 times the square root of S_O, where S_O is the original cross-sectional area) may be used when agreed upon between the supplier and purchaser.

of SI units. Annex A of that standard provides conversion tables and Annex B provides rules for conversion and significance.

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 Methods 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/E165M 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 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-28 chromium-6 molybdenum forgings used in the manufacture of medical devices that receive no subsequent metallurgical processing.

X1.2 Published data[4,5] 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.

[4] 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.

[5] 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 While no known surgical implant material has ever been shown to be completely free of adverse reactions in the human body, long term clinical experience has shown an acceptable level of biological response can be expected if the material is used in appropriate applications. However, this specification covers the raw material and not finished medical devices, where the design and fabrication of the device can impact biological response.

SUMMARY OF CHANGES

Committe F04 has identified the location of selected changes to this standard since the last issue (F799 – 11) that may impact the use of this standard. (Approved May 15, 2019.)

(1) Updated specification to agree with the F04.12 template language and terminology.

(2) SI units made the primary focus in the text and Table 1.
(3) Updated the biocompatibility statement in X2.3.