Designation: F75 – 12

Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)[1]

This standard is issued under the fixed designation F75; 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 chemical, mechanical, and metallurgical requirements for cobalt-28 chromium-6 molybdenum alloy unfinished investment product castings for surgical implant applications and casting alloy in the form of shot, bar, or ingots to be used in the manufacture of surgical implants. This specification does not apply to completed surgical implants made from castings.

1.2 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]

A957 Specification for Investment Castings, Steel and Alloy, Common Requirements, for General Industrial Use

E3 Guide for Preparation of Metallographic Specimens

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

E165 Practice for Liquid Penetrant Examination for General Industry

E354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys

E407 Practice for Microetching Metals and Alloys

E601 Test Method for Measuring Electromotive Force (emf) Stability of Base-Metal Thermoelement Materials with Time in Air

F629 Practice for Radiography of Cast Metallic Surgical Implants

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

2.2 *Aerospace Material Specification:*[3]

AMS 2248 Chemical Check Analysis Limits: Corrosion and Heat Resistant Steels and Alloys, Maraging and Other Highly-Alloyed Steels, and Iron Alloys

AMS 2269 Chemical Check Analysis Limits: Nickel, Nickel Alloys and Cobalt Alloys

2.3 *ISO Standards:*[4]

ISO 5832-4 Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy

ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems—Requirements

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *investment casting, n*—a metal casting that is produced in a mold obtained by investing (surrounding) an expendable pattern with a ceramic slurry that is allowed to solidify. The expendable pattern may consist of wax, plastic, or other material and is removed prior to filling the mold with liquid metal.

3.1.2 *master heat, n*—a quantity of metal processed in a single furnace or refining vessel at one time in such a manner as to produce the desired composition and properties.

3.1.3 *sub-heat, n*—a portion of a master heat remelted without additional processing for pouring into castings. *Synonyms*: melt, production heat.

NOTE 1—Terminology section in accordance with Specification A957.

[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.

Current edition approved May 15, 2012. Published June 2012. Originally approved in 1967. Last previous edition approved in 2007 as F75 – 075. DOI: 10.1520/F0075-12.

[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 Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

[4] 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. Ordering Information

4.1 Include with inquiries and orders for material under this specification the following information:

4.1.1 Quantity (number of product castings or weight of casting alloy),

4.1.2 ASTM designation and date of issue,

4.1.3 Units to be certified—SI or inch-pound.

4.1.4 Form (product casting, shot, bar, ingot),

4.1.5 Applicable dimensions or drawing number,

4.1.6 Condition (as-cast, hot isostatically pressed (HIP), solution annealed, and so forth),

4.1.7 Special tests, if any, and

4.1.8 Other requirements.

5. Materials and Manufacturing Requirements for Product Castings

5.1 Final thermal processing for castings, if any, shall be specified by mutual agreement between the supplier and purchaser.

5.2 Castings shall be free of visible investment shell material and scale when examined without magnification.

5.3 Welding may be used to repair castings as agreed upon between supplier and purchaser.

5.3.1 Weld repair shall be performed in accordance with written procedures by individuals certified to perform those procedures.

5.3.2 Weld filler metal conforming to the chemistry of Table 1 shall be used when it is needed.

5.3.3 Weld repair, if any, shall be performed before final thermal processing.

NOTE 2—Under certain circumstances, a weld repair may act as a stress riser. Therefore, care should be exercised in the location and extent of weld repair as it relates to regions of the implant where significant stresses might occur.

6. Chemical Requirements

6.1 Both product castings and casting alloy shall conform to the chemical requirements prescribed in Table 1. The supplier shall not ship material that is outside the limits specified in Table 1.

6.1.1 Chemical analysis shall be performed on a representative specimen of a sub heat cast from each master heat using the same general foundry procedures used for casting implants.

6.1.2 Requirements for the major and minor elemental constituents are listed in Table 1. Also listed are important residual elements. Analysis for elements not listed in Table 1 is not required to verify compliance with this specification.

6.2 *Product Analysis:*

6.2.1 Product analysis tolerances do not broaden the specified heat analysis requirements but cover variations in the measurement of chemical content between laboratories . The product analysis tolerances shall conform to the product tolerances in Table 2.

6.2.2 The product analysis is either for the purpose of verifying the composition of a heat or manufacturing lot or to determine variations in the composition within the heat.

6.2.3 Acceptance or rejection of a heat or manufacturing lot of material may be made by the purchaser on the basis of this product analyses. Product analysis outside the tolerance limits allowed in Table 2 are cause for rejection of the product. A referee analysis may be used if agreed upon by supplier and purchaser.

7. Mechanical Requirements

7.1 *Tensile Properties for Product Castings:*

7.1.1 As-cast material shall conform to the mechanical property requirements given in Table 3 when tested in accordance with Test Methods E8/E8M.

7.1.2 Tension test specimens shall be melted and cast from a sub heat of each master heat by the same general procedures used in casting the surgical implants or machined from surgical implant castings.

TABLE 1 Chemical Composition

Element	Composition, % (Mass/Mass)	
	min	max
Chromium	27.00	30.00
Molybdenum	5.00	7.00
Nickel	...	0.50
Iron	...	0.75
Carbon	...	0.35
Silicon	...	1.00
Manganese	...	1.00
Tungsten	...	0.20
Phosphorous	...	0.020
Sulfur	...	0.010
Nitrogen	...	0.25
Aluminum	...	0.10
Titanium	...	0.10
Boron	...	0.010
Cobalt[A]	balance	balance

[A] Approximately equal to the difference of 100 % and the sum percentage of the other specified elements. The percentage of the cobalt difference is not required to be reported.

TABLE 2 Product Analysis Tolerances[A,B]

Element	Tolerance Under the Minimum or Over the Maximum Limit, % (Mass/Mass)[C]
Chromium	0.30
Molybdenum	0.15
Nickel	0.05
Iron	0.03
Carbon	0.02
Silicon	0.05
Manganese	0.03
Tungsten	0.04
Phosphorous	0.005
Sulfur	0.003
Nitrogen	0.02[D]
Aluminum	0.02
Titanium	0.02
Boron	0.002

[A] See Test Methods E354.
[B] Refer to AMS Standard 2269 for chemical check analysis limits (except nitrogen).
[C] For elements in which only a maximum percentage is indicated, the "under minimum limit" is not applicable.
[D] Refer to AMS 2248 for chemical check analysis limits.

TABLE 3 As-Cast Mechanical Requirements

Property	
Ultimate tensile strength, min, MPa (psi)	655 (95 000)
Yield strength, (0.2 % offset), min, MPa (psi)	450 (65 000)
Elongation,[A] min, %	8
Reduction of area, min, %	8

[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 times the square root of S_o, where S_o is the original cross-sectional area.)

7.1.3 Specimens may be cast, ground, or machined to final dimensions in accordance with the 0.25 in. (6.35 mm) diameter specimen in Fig. 8 of Test Methods E8/E8M.

7.1.4 Perform at least two tension tests per master heat. Should any of these test pieces not meet the specified requirements, test two additional representative test pieces, in the same manner, for each failed test piece. The master heat shall be considered in compliance only if all additional test pieces meet the specified requirements.

7.1.5 Tensile tests results for which any specimen fractures outside the gage length shall be considered valid if both the elongation and reduction of area meet the minimum requirements specified. If either the elongation or reduction of area is less than the minimum requirement, invalidate the specimen and retest. Retest one specimen for each invalidated specimen.

7.1.6 If castings are supplied in a heat-treated condition, tensile property requirements shall be agreed upon between supplier and purchaser.

7.2 *Tensile Properties for Casting Alloy:*

7.2.1 As-cast material shall conform to the mechanical property requirements given in Table 3 when tested in accordance with Test Methods E8/E8M.

7.2.2 Tension∈ test specimens shall be melted and cast from a sub heat of each master heat by the same general procedures used in casting of the surgical implants

7.2.3 Specimens may be cast, ground, or machined to final dimensions in accordance with the 0.25 in. (6.35 mm) diameter specimen in Fig. 8 of Test Methods E8/E8M.

7.2.4 Perform at least two tension tests per master heat. Should any of these test pieces not meet the specified requirements, test two additional representative test pieces, in the same manner, for each failed test piece. The master heat shall be considered in compliance only if all additional test pieces meet the specified requirements.

7.2.5 Tensile tests results for which any specimen fractures outside the gage length shall be considered valid if both the elongation and reduction of area meet the minimum requirements specified. If either the elongation or reduction of area is less than the minimum requirement, invalidate the specimen and retest. Retest one specimen for each invalidated specimen.

8. Special Testing for Product Castings

8.1 *Liquid Penetrant Examination*—Sampling plans and acceptance criteria shall be mutually agreed upon by supplier and purchaser. Individual parts should be examined in accordance with Test Method E601 or Test Method E165, as appropriate for the surface condition of the casting being tested.

8.2 *Radiographic Examination*—Sampling plans and acceptance criteria shall be mutually agreed upon by supplier and purchaser. Radiographic examination shall be in accordance with Practice F629.

8.3 *Metallography*—The microstructural requirements and frequency of examinations shall be mutually agreed upon by supplier and purchaser. Specimen preparation shall be in accordance with Guide E3 and Practice E407.

8.4 *Hardness:*

8.4.1 Materials conforming to this specification will typically have a hardness of 25 to 35 HRC in the as-cast condition. The hardness determination shall be performed in accordance with Test Methods E18.

8.4.2 Hardness values are for information only and shall not be used as criteria for rejection.

9. Significance of Numerical Limits

9.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or 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.

10. Certification

10.1 The supplier shall provide a certification 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.

10.1.1 If the supplier and purchaser are one and the same, equivalent internal documentation shall be acceptable in lieu of certification.

11. Quality Program Requirements

11.1 The supplier shall maintain a quality program as defined in ISO 9001 or similar quality program.

12. Keywords

12.1 castings—surgical; cobalt alloys (for surgical implants); cobalt-chromium-molybdenum-metals (for surgical implants); cobalt alloys

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The mechanical properties listed in Table 3 are used to verify the capability of the alloy to produce castings of acceptable strength and ductility. For consistency of test results, it is advisable to subject test bars to the same radiographic and penetrant requirements as will be used for the castings they represent.

X1.2 Cast microstructure and mechanical properties are dependent on cross sectional thickness. The mechanical properties measured on as-cast ¼-in. diameter test bars may not be the same as those in castings of different cross-sectional thickness.

X1.3 Various heat treatments, including hot isostatic pressing, solution annealing, and sintering, may be used on cobalt-28 chromium-6 molybdenum alloy surgical implant castings. This specification is not intended to cover the effects of such processes.

X1.4 If castings are straightened, bent or welded, they may require subsequent annealing or special testing per Section 8.

X1.5 Because of the wide variety of devices made from this alloy, 100 % radiographic inspection may not be required.

X1.6 The approximate ISO standard equivalent for this material is ISO 5832-4. (Such ISO standards are listed for reference only. Although ISO standards are similar to the corresponding ASTM International standards, they are not always identical. Use of an ISO standard in addition to or instead of a preferred ASTM International standard may be negotiated between purchaser and supplier.)

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this standard has been used successfully in human implant applications in contact with soft tissue and bone for over a decade. Because of the well characterized level of biological response exhibited by this alloy, it has been used as a control material in Practice F981.

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 of the use of the material referred to in this standard has shown that an acceptable level of biological response can be expected, if the 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 (F75 – 07) that may impact the use of this standard. (Approved May 15, 2012.)

(1) Specification updated to agree with the F04.12 template language.