Designation: F 75 – 01

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 F 75; 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 provides the 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 inch-pound units are to be regarded as the standard. The SI equivalents of inch-pound units may be approximate.

2. Referenced Documents

2.1 *ASTM Standards:*

E 3 Practice for Preparation of Metallographic Specimens[2]
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 165 Test Method for Liquid Penetrant Examination[3]
E 407 Practice for Microetching Metals and Alloys[2]
E 601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[4]
E 629 Practice for Radiography of Cast Metallic Surgical Implants[5]
F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[6]

2.2 *Aerospace Material Specification:*[7]

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:*[8]

ISO 5832-4 Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy
ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

2.4 *American Society for Quality Standard:*[9]

ASQ Cl 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 (number of product castings or weight of casting alloy),
3.1.2 ASTM designation and date of issue,
3.1.3 Form (product casting, shot, bar, ingot),
3.1.4 Applicable dimensions or drawing number,
3.1.5 Condition (as-cast, hot isostatically pressed (HIP), solution annealed, and so forth),
3.1.6 Special tests, if any, and
3.1.7 Other requirements.

4. Materials and Manufacturing Requirements for Product Castings

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

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

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

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

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

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

[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 14.03.
[5] Discontinued; See 1996 *Annual Book of ASTM Standards*, Vol 11.05.
[6] *Annual Book of ASTM Standards*, Vol 13.01.
[7] Available from Society of Automotive Engineers, 400 Commonwealth Dr., Warrendale, PA 15096-0001.
[8] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.
[9] 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.**

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	balance	balance

TABLE 2 Product Analysis Tolerances[A]

Element	Tolerance,[B,C] % (Mass/Mass)
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] Refer to AMS Standard 2269 for chemical check analysis limits.
[B] Under the minimum limit or over the maximum limit.
[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.

NOTE 1—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.

5. Chemical Requirements

5.1 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. Chemical analysis shall be performed on a representative specimen cast from each master heat using the same general procedures used in casting implants.

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

5.2 *Product Analysis* —The product analysis is either for the purpose of verifying the composition of a heat or lot or to determine variations in the composition within the heat.

5.2.1 Acceptance or rejection of a heat or lot of material may be made by the purchaser on the basis of this product analysis.

5.2.2 Product analysis tolerances do not broaden the specified chemical requirements but instead cover variations between laboratories in the measurement of chemical content. Product analysis limits shall be as specified in Table 2.

6. Mechanical Requirements

6.1 *Tensile Properties for Product Castings*:

6.1.1 As-cast material shall conform to the mechanical property requirements given in Table 3 when tested in accordance with Test Methods E 8.

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

6.1.3 A minimum of two tension test specimens per heat shall be tested. If one specimen fails the specified mechanical requirements, two additional specimens shall be tested and both must pass.

TABLE 3 As-Cast Mechanical Requirements

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

[A] Elongation of material 0.062 in. (1.575 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 0.062 in. (1.575 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. ($5.65\sqrt{S_o}$, where S_o is the original cross-sectional area.)

6.1.4 Tension test results for which any specimen fractures outside the gage length shall be considered invalid and a replacement specimen shall be tested in accordance with Test Methods E 8.

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

6.2 *Tensile Properties for Casting Alloy*:

6.2.1 As-cast material shall conform to the mechanical property requirements given in Table 3 when tested in accordance with Test Methods E 8.

6.2.2 Tension test specimens shall be melted and cast under casting procedures agreed upon between supplier and purchaser.

6.2.3 A minimum of two tension test specimens per master heat shall be tested. If one specimen fails the specified mechanical requirements, two additional specimens shall be tested and both must pass.

6.2.4 Tension test results for which any specimen fractures outside the gage length shall be considered acceptable, if the reduction of area meets the minimum requirements specified. If the reduction of area is less than the minimum requirement, discard the test results and retest.

7. Special Testing for Product Castings

7.1 *Liquid Penetrant Examination*—Sampling plans and acceptance criteria shall be mutually agreed upon by supplier