



Designation: F75 – 12

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

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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

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.

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.

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.

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.

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 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.