



Designation: F75 – 23

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 nonconformance with the standard.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

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

- A957/A957M Specification for Investment Castings, Steel and Alloy, Common Requirements, for General Industrial Use
- E3 Guide for Preparation of Metallographic Specimens

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.

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/E165M Practice for Liquid Penetrant Testing 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

F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

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 Insertion into Bone

IEEE/ASTM SI 10 American National Standard for Metric Practice

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

ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

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

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/A957M.

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.

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.

6.1.2 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.

6.1.3 All commercial metals contain small amounts of elements other than those which are specified. It is neither practical nor necessary to specify limits for unspecified elements, whether residual elements or trace elements that can be present. The producer is permitted to analyze for unspecified elements and is permitted to report such analyses. The presence of an unspecified element and the reporting of an analysis for that element shall not be a basis for rejection.

6.1.4 Intentional elemental additions other than those specified in Table 1 are not permitted.

6.1.5 Analysis for elements not listed in Table 1 is not required to verify compliance with this specification, unless previously agreed to between purchaser and supplier.

6.2 *Product (Check) Analysis*—The product (check) analysis tolerances shall conform to the product tolerances in Table 2 per AMS 2269. Product analysis tolerances do not broaden the specified heat (ladle or ingot) analysis requirements but cover variations between laboratories in the measurement of chemical content.

6.2.1 Product (check) analysis limits are not for the supplier's/producer's use at acceptance testing. Product analysis limits are not permitted to be applied to ladle or ingot analysis. The supplier/producer shall not ship material that is outside the limits specified in Table 1.

6.2.2 The product (check) analysis is one performed by the purchaser or the supplier of metal after it has been worked into semi-finished or finished forms, or fabricated into parts, and 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 (check) analysis. Product (check) analysis outside the tolerance limits allowed in Table 2 are cause for rejection of the