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Designation: F 75 – 98

Standard Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products 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 covers the requirements for cobalt-28 chromium-6 molybdenum casting alloy in, shot, bar, or ingot form for surgical implant applications.

1.2 This specification also describes the chemical analysis requirements for investment castings produced from the alloy described in this specification. This specification is not concerned with any other specific requirements or recommendations for investment castings.

1.3 Requirements for powder produced from the alloy described in this specification are provided in Specification F 1377.

1.4 The values stated in inch-pound units are to be regarded as the standard.

2. Referenced Documents

2.1 *ASTM Standards:*

E 8 Test Methods of Tension Testing of Metallic Materials[2]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[2]

E 354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys[3]

F 981 Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implants with Respect to Effect of Materials in Muscle and Bone[4]

F 1377 Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS-R 30075)[4]

2.2 *Aerospace Material Specification:*

AMS 2248 Chemical Check Analysis Limits, Wrought Heat, and Corrosion-Resistant Steels and Alloys[5]

AMS 2269 Chemical Check Limits, Wrought Nickel Alloys and Cobalt Alloys[5]

2.3 *American Society for Quality Standard:*

ASQ Cl General Requirements for a Quality Program[6]

3. Significance and Use

3.1 This specification characterizes the composition and properties in the starting material (for example, remelt alloy), used to investment cast cobalt-28 chromium-6 molybdenum alloy surgical implants.

4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:

4.1.1 Quantity (weight),

4.1.2 ASTM designation,

4.1.3 Mechanical properties (if applicable),

4.1.4 Form (shot, bar, ingot),

4.1.5 Applicable dimensions or print number,

4.1.6 Condition,

4.1.7 Special tests, and

4.1.8 Other requirements.

5. Chemical Requirements

5.1 The heat analysis shall conform to the requirements as to chemical composition prescribed in Table 1. The product analysis tolerances shall conform to the requirements prescribed in Table 2. Product analysis tolerances do not broaden the specified heat analysis, but cover variation between laboratories in the measurement of chemical content.

5.2 Investment castings produced from alloy conforming to this specification shall also conform to the chemical requirements of Table 1.

5.3 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.

5.4 For referee purposes, Test Methods E 354 shall be used.

6. Mechanical Requirements

6.1 *Tensile Properties*:

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

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[1] This specification is under the jurisdiction of ASTM Committee F-4 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 03.05.

[4] *Annual Book of ASTM Standards*, Vol 13.01.

[5] Available from Society of Automotive Engineers, 400 Commonwealth Drive, Warrendale, PA 15096.

[6] Available from American Society for Quality, 611 East Wisconsin Ave., Milwaukee, WI 53203.

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TABLE 1 Chemical Requirements

Element	Composition, %	
	min	max
Chromium	27.0	30.00
Molybdenum	5.0	7.00
Nickel	...	1.00
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	...	0.30
Boron	...	0.01
Cobalt	balance	balance

TABLE 2 Product Analysis Tolerances[A]

Element	Tolerance Under the Minimum Limit or Over the Maximum Limit[B]
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	0.005
Aluminum	0.02
Boron	0.002

[A] Refer to AMS Standard 2269C for Chemical Check Analysis Limits.
[B] For elements where only a maximum percentage is indicated, the "under minimum limit" is not applicable.

6.1.2 Tension specimens shall be melted and cast from the metal under casting procedures agreed upon between supplier and purchaser. The test methods shall be in accordance with the ¼-in. (6.35-mm) diameter specimen in Fig. 8 of Test Methods E 8 which may have a ground finish on the reduced section.

6.1.3 Four tension specimens shall be tested. If all results, or three of the four results, of the tension tests confrom to the requirements given in Table 3, the material is in compliance with the tensile property requirements of this standard. If two or more of the initial results do not conform to the requirements given in Table 3, an additional four tensile specimens shall be tested. For the material lot to be in compliance with the tensile property requirements of this standard, all four of the additional tensile test results must conform to the requirements given in Table 3.

TABLE 3 As-Cast Mechanical Property Requirements

Property	
Tensile strength, min, psi (MPa)	95 000 (655)
Yield strength (0.2 % offset), min, psi (MPa)	65 000 (450)
Elongation, min, %	8
Reduction of area, min, %	8

6.1.4 Tension test results for any specimen which fractures outside of the gage length shall be considered invalid and void, and a replacement shall be tested.

6.2 *Hardness*:

6.2.1 Materials conforming to this specification typically will have Rockwell C-Scale hardness of 25 to 35 HRC as in the as-cast condition. The hardness determination shall be performed in accordance with Test Methods E 18.

6.2.2 Hardness values are for guidelines only and shall not be used as a criteria for rejection.

7. Certification

7.1 A certification shall be provided by the manufacturer of the material that the material was manufactured and tested in accordance with this specification. A report of the test results shall be furnished at the time of shipment.

8. Quality Program Requirements

8.1 The producer shall maintain a quality program, for example, such as defined in ASQ C1.

9. Keywords

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

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The chemical requirements in Table 1 reflect industry practice at the time of this revision. Residual element requirements are in agreement with the guidelines established by the International Organization for Standardization for surgical implant alloys.

X1.2 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 which they represent.

X1.3 Cast microstructure and mechanical properties are dependent on cross sectional thickness. The mechanical properties measured on as-cast ¼ inch diameter test bars will not be the same as those in castings of different cross sectional thickness.

X1.4 Various heat treatments, including hot isostatic pressing, solution annealing, and sintering are used on Cobalt-28 Chromium-6 Molybdenum alloy surgical implant castings. This specification is not intended to cover the effects of such heat treatments.

X1.5 Changes made from the previous document include a change in title, addition of the UNS number, the addition of elements in Table 1; Chemical Requirements, new residual element language, new tension testing requirements, a statement that castings made from this alloy shall also conform to the chemical requirements of Table 1 and the addition of Biocompatibility language in the Appendix.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this standard has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the well characterized level of biological response exhibited by this alloy, it has been used as a control material in Practice F 981.

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.

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