



Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS-R30075)¹

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1. Scope

1.1 This specification covers the requirements for cobalt-28 chromium-6 molybdenum alloy powders for use in fabricating coatings on cobalt-28 chromium-6 molybdenum alloy orthopedic implants.

1.2 Powders covered under this specification may be used to form coatings by sintering or thermal spraying techniques.

1.3 This specification covers powder requirements only. It does not address properties of the coatings formed from them.

1.4 The values stated in inch-pound units are to be regarded as the standard. The SI units given in parentheses are for information only.

2. Referenced Documents

2.1 ASTM Standards:

B 214 Test Method for Sieve Analysis of Metal Powders²

B 215 Practices for Sampling Finished Lots of Metal Powders²

E 11 Specification for Wire-Cloth Sieves for Testing Purposes³

E 354 Test Methods for Chemical Analysis of High Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys⁴

F 75 Specification for Cobalt-28 Chromium-6 Molybdenum Casting Alloy and Cast Products for Surgical Implants (UNS-R30075)⁵

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone⁵

2.2 ASQ Standards:

C1 General Requirements for a Quality Program⁶

3. Significance and Use

3.1 Coatings formed from metallic powders have become widely used as a means of improving tissue attachment to uncemented orthopedic joint prosthesis. Such coatings have also been demonstrated to improve bonding of acrylic cement to prostheses. This specification addresses the special requirements of the metal powders used to form these coatings.

4. Materials and Manufacture

4.1 Powders may be manufactured by the rotating electrode process, inert gas atomization, or other methods capable of producing powder meeting the requirements of this specification.

5. Chemical Composition

5.1 The heat analysis of stock used to manufacture the powder shall conform to the chemical analysis set forth in Table 1 of Specification F 75.

5.2 The product analysis tolerance shall conform to the requirements set forth in Table 2 of Specification F 75.

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

6. Particle Size

6.1 Powder shall be sieved to the customer's requirements with screens conforming to Specification E 11. Analysis of the sieved powder for conformance to customer's particle size range requirements shall be according to Test Method B 214. Powder sampling shall be according to Test Method B 215.

7. Cleanliness

7.1 Powder shall be handled at all times so as to minimize possible contamination with nonmetallic materials or other metal alloy powders, or both.

7.2 Powder cleanliness shall be determined by examining a representative sample comprising at least 1 in.² (645 mm²) of a closely packed mono-layer of powder at 20× magnification. No foreign material shall be visible under these conditions.

8. Special Requirements

8.1 Various materials known as processing aids may be added to the powder to provide enhanced processability and, if applicable, the powder supplier shall include this information on the material certification.

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 02.05.

³ Annual Book of ASTM Standards, Vol 14.02.

⁴ Annual Book of ASTM Standards, Vol 03.05.

⁵ Annual Book of ASTM Standards, Vol 13.01.

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