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AMERICAN SOCIETY FOR TESTING AND MATERIALS
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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 Powders[2]

B 215 Practices for Sampling Finished Lots of Metal Powders[2]

E 11 Specification for Wire-Cloth Sieves for Testing Purposes[3]

E 354 Test Methods for Chemical Analysis of High Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys[4]

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 Bone[5]

2.2 *ASQ Standards:*

C1 General Requirements for a Quality Program[6]

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 mm^2) 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.

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[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devicesand is the direct responsibility of Subcommittee F04.12on 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.

8.2 Processing aids shall have no detrimental effect on the corrosion resistance and biocompatibility of the final coating.

9. Certification

9.1 Powder shipped under this specification shall be accompanied by a certification that includes the following:

9.1.1 ASTM designation,

9.1.2 Quantity (weight),

9.1.3 Method of manufacture,

9.1.4 Chemical analysis in accordance with 5.1,

9.1.5 Sieve analysis in accordance with 6.1,

9.1.6 Powder cleanliness in accordance with 7.2,

9.1.7 Special requirements in accordance with 8.1, and

9.1.8 Other requirements.

10. Quality Program Requirements

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

10.2 The manufacturer of surgical implants shall be assured of the producer's quality program for conformance to the intent of ASQ C1 or other recognized program.

11. Keywords

11.1 coatings, metallic; cobalt alloys (for surgical implants); metals (for surgical implants, cobalt alloys); orthopedic medical devices (cobalt alloys); porous coatings; powder

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 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.

X1.2 It should be recognized that the heat treatments used to form porous coatings can create microstructures which are substantially different from investment cast F 75 alloy. Porous coated implants also exhibit much greater surface area than monolithic implants. For these reasons, the biocompatibility and corrosion behavior must be characterized on finished coatings.

X1.3 Pore size and morphology are important factors influencing tissue ingrowth and acrylic penetration of porous coatings. Particle size and shape are critical to controlling the pore size and morphology in the final coating. Particle size is conventionally controlled by screening. The referenced ASTM and MPIF (Metal Powder Industries Federation) standards allow comparison of powder to a manufacturer's specifications for a given coating process.

X1.4 Other process parameters are also critical to determining final pore size and morphology in the final coating. Because these parameters are not directly related to the chemical and physical characteristics of the starting powder, they are not addressed in this standard.

X1.5 The requirements for powder cleanliness minimize contaminants which might adversely affect either the biocompatibility or the finished coatings or the ability to properly bond the coating during manufacturing. The test method in 7.2 is commonly used for relatively coarse spherical powders used to fabricate sintered porous coatings. Other types of powders may require different methods for cleanliness characterization. The development and implementation of such methods are the responsibility of the implant manufacturer.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition, free of processing aids (see Section 8), covered by this standard has been employed successfully in human implant applications is 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.