Designation: F 1377 – 04

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

This standard is issued under the fixed designation F 1377; 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-28chromium-6molybdenum alloy powders for use in fabricating coatings on cobalt-28chromium-6molybdenum 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:* [2]

B 214 Test Method for Sieve Analysis of Metal Powders

B 215 Practices for Sampling Finished Lots of Metal Powders

E 11 Specification for Wire Cloth and Sieves for Testing Purposes

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

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

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

2.2 *ASQ Standards:*

C1 General Requirements for a Quality Program[3]

3. Ordering Information

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

3.1.1 Quantity,

3.1.2 ASTM designation and date of issue,

3.1.3 Method of powder manufacturing,

3.1.4 Chemistry requirements,

3.1.5 Sieve analysis requirements,

3.1.6 Special tests, if any, and

3.1.7 Other requirements.

4. Significance and Use

4.1 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.

5. Materials and Manufacture

5.1 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.

6. Chemical Composition

6.1 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.

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

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

[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.

[3] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203.

*A Summary of Changes section appears at the end of this standard.

7. Sieve Analysis Requirements

7.1 Powder shall be sieved to the customer's requirements with screens conforming to Specification E 11. Sieve analysis testing of the sieved powder for conformance to purchaser's particle size range requirements shall be performed according to Test Method B 214. Powder sampling shall be performed according to Test Method B 215.

8. Cleanliness Requirements

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

8.2 Powder cleanliness shall be determined by examining a representative sample of the powder. Powder sampling shall be performed according to Practices B 215. Powder testing shall be performed by examining either (*a*) at least 1 in.^{2} (645 mm^2) of a closely packed mono-layer of powder at 20× , or (*b*) by an alternative testing practice, as agreed upon between purchaser and supplier. No foreign material shall be visible under these test conditions.

9. Certification

9.1 Certification that the material meets the requirements of the specification shall be provided by the supplier. A report of the test results shall be furnished at the time of shipment.

10. Quality Program Requirements

10.1 The powder supplier shall maintain a quality program, such as that which is defined in ASQ C1.

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 standards allow comparison of powder to a purchaser'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 specification.

X1.5 The requirements for powder cleanliness minimize contaminants which might adversely affect either the biocompatibility of the finished coatings or the ability to properly bond the coating during manufacturing. The test method in 8.2 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.

X1.6 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. Processing aids shall have no detrimental effect on the corrosion resistance, biocompatibility, or adhesion of the final coating.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification 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 specification has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.