Designation: F1377 – 13

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

This standard is issued under the fixed designation F1377; 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 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 non-conformance with the standard.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

B214 Test Method for Sieve Analysis of Metal Powders

B215 Practices for Sampling Metal Powders

E11 Specification for Woven Wire Test Sieve Cloth and Test Sieves

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E354 Test Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)

2.2 *ISO Standard:*[3]

ISO 9001 Quality Management Standard

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 Specifications F75 or F1537 (Alloy 1 and Alloy 2 only).

6.2 The product analysis tolerance shall conform to the requirements set forth in Table 2 of Specifications F75 or F1537.

6.3 For referee purposes, Test Methods E354 shall be used.

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

Current edition approved June 1, 2013. Published August 2013. Originally approved in 1992. Last previous edition approved in 2008 as F1377 – 08. DOI: 10.1520/F1377-13.

[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 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**

7. Sieve Analysis Requirements

7.1 Powder shall be sieved to the customer's requirements with screens conforming to Specification E11. Sieve analysis testing of the sieved powder for conformance to purchaser's particle size range requirements shall be performed according to Test Method B214. Powder sampling shall be performed according to Test Method B215.

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 B215. 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. Significance of Numerical Limits

9.1 The following applies to all specified numerical limits in this specification. To determine conformance to these limits, an observed or calculated value shall be rounded to the nearest unit in the last right hand digit used in expressing the specification limit, in accordance with the Rounding Method of Practice E29.

10. Certification

10.1 The supplier shall provide a certification that the material was manufactured in accordance with the requirements of the specification. A report of the test results shall be furnished to the purchaser at the time of shipment.

11. Quality Program Requirements

11.1 The powder supplier shall maintain a quality program or quality management system, such as that which is defined in ISO 9001.

12. Keywords

12.1 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 F75 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.

X1.7 The processing behavior of the powder can be affected by variations in the chemical composition of the material, particularly the carbon content. Sintering and thermal spray practices may need to be modified depending on the chemical composition of the powder.

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 with a well-characterized level of biological response.

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.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F1377 – 08) that may impact the use of this standard. (Approved June 1, 2013.)

(1) Removed ASQ C1 from Sections 2 and 11.
(2) Added Section 9.1 and added E29 and F1537 to Section 2.
(3) Added F1537 Alloy 1 and Alloy 2 to Section 6.
(4) Added X1.7.
(5) Editorial corrections have been made in order to meet terminology and formatting guidelines established for implant material standards.