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Designation: ~~F1377 – 13~~ F1377 – 21

Standard Specification for Cobalt-28Chromium-6Molybdenum Powder for ~~Coating of Orthopedic Implants (UNS R30075)~~Medical Devices (UNS R30075, UNS R31537, and UNS R31538)[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.~~medical devices.

1.2 Powders covered under this specification may be used to form coatings by sintering or thermal spraying ~~techniques.~~ techniques, or in metal injection molding or additive manufacturing.

1.3 This specification covers powder requirements only. It does not address properties of the coatings or components 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 are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems shall not be combined.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

B214 Test Method for Sieve Analysis of Metal Powders
B215 Practices for Sampling Metal Powders
B822 Test Method for Particle Size Distribution of Metal Powders and Related Compounds by Light Scattering
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

[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.

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

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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:~~Standards:*[3]
ISO 9001 Quality Management Standard
ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

3. Ordering Information

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

3.1.1 ~~Quantity,~~Quantity;

3.1.2 ASTM designation and date of ~~issue,~~issue;

3.1.3 Method of powder ~~manufacturing,~~manufacturing;

3.1.4 Chemistry ~~requirements,~~requirements;

3.1.5 ~~Sieve analysis requirements,~~Particle size requirements;

3.1.6 Special tests, if ~~any,~~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 prostheses. Such coatings have also been demonstrated to improve bonding of acrylic cement to prostheses. This specification addresses the special~~ Powders used to form coatings have been widely used in orthopedics, including orthopedic joint prostheses. The use of powders for medical devices has expanded greatly with new technologies such as metal injection molding and additive manufacturing. This specification provides a framework for the requirements of the metal powders used as raw materials to form ~~these coatings.~~ coatings and in these newer technologies. This specification is not intended to address special requirements specific to any of these technologies.

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~~Specification 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~~Specification F75 or F1537.

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

7. ~~Sieve Analysis~~Particle Size Requirements

7.1 Powder shall be sieved to the customer's requirements with screens conforming to Specification E11. ~~Sieve~~ Particle size

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

analysis ~~testing~~ of the sieved powder for conformance to purchaser's particle size range requirements shall be performed according to Test Method B214 or B822. Powder sampling shall be performed according to ~~Test Method~~ Practices 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~~*1*) at least ~~1 in.~~645 mm^2 ~~(645 mm~~(1 in.^{2}) of a closely packed mono-layer of powder at ~~20× ,~~ 20×, or (~~b~~*2*) 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~~ right-hand digit used in expressing the specification limit, in accordance with the ~~Rounding Method~~rounding method of Practice E29.

10. Certification

10.1 The supplier shall provide a certification that the material was ~~manufactured~~tested in accordance with the requirements of ~~the specification.~~ this specification and met all requirements. 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.~~9001 or ISO 13485, or similar quality program.

12. Keywords

12.1 additive manufacturing; coatings, metallic; cobalt alloys (for surgical implants); metal injection molding; metal laser sintering; metals (for surgical implants, cobalt alloys); orthopedic medical devices (cobalt alloys); porous coatings; ~~powder~~powder; selective laser melting

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the composition and properties of cobalt-28chromium-6molybdenum alloy powders in the manufacturing of medical devices.

X1.2 ISO standards are listed for reference only. Although ISO standards are similar to the corresponding ASTM standards, they are not identical. Use of an ISO standard in addition to or instead of the preferred ASTM standard may be agreed upon between the purchaser and supplier.

X1.3 Coatings formed from metallic powders have become widely used as a means of improving tissue attachment to uncemented orthopedic joint ~~prosthesis.~~prostheses. Such coatings have also been demonstrated to improve bonding of acrylic cement to prostheses.

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