



Designation: F1377 – 21

Standard Specification for Cobalt-28Chromium-6Molybdenum Powder for 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 cobalt-28chromium-6molybdenum alloy medical devices.

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

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 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;
- 3.1.2 ASTM designation and date of issue;
- 3.1.3 Method of powder manufacturing;
- 3.1.4 Chemistry requirements;
- 3.1.5 Particle size requirements;
- 3.1.6 Special tests, if any; and
- 3.1.7 Other requirements.

4. Significance and Use

4.1 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

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.

Current edition approved Dec. 1, 2021. Published December 2021. Originally approved in 1992. Last previous edition approved in 2013 as F1377 – 13. DOI: 10.1520/F1377-21.

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