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Standard Specification for Metal Injection Molded Cobalt-28Chromium-6Molybdenum Components for Surgical Implant Applications[1]

This standard is issued under the fixed designation F2886; 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 chemical, mechanical, and metallurgical requirements for metal injection molded (MIM) cobalt-28chromium-6molybdenum components to be used in the manufacture of surgical implants

1.2 The MIM components covered by this specification may have been densified beyond their as-sintered density by post-sinter processing.

1.3 *Units*—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 nonconformance with the standard.

1.4 *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]

B243 Terminology of Powder Metallurgy

B311 Test Method for Density of Powder Metallurgy (PM) Materials Containing Less Than Two Percent Porosity

B923 Test Method for Metal Powder Skeletal Density by Helium or Nitrogen Pycnometry

E3 Guide for Preparation of Metallographic Specimens

E8/E8M Test Methods for Tension Testing of Metallic Materials

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

E165/E165M Practice for Liquid Penetrant Testing for General Industry

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

E407 Practice for Microetching Metals and Alloys

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

F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

F629 Practice for Radiography of Cast Metallic Surgical Implants

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

IEEE/ASTM SI 10 American National Standard for Use of the International System of Units (SI): The Modern Metric System

2.2 *ISO Standards:*[3]

ISO 6892 Metallic Materials Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems—Requirements

2.3 *AMS Standards:*[4]

AMS 2269 Chemical Check Analysis Limits, Nickel, Nickel Alloys and Cobalt Alloys

AMS 2248 Chemical Check Analysis Limits, Corrosion and Heat Resistant Steels and Alloys, Maraging and Other Highly-Alloyed Steels, and Iron Alloys

2.4 *MPIF Standards:*[5]

MPIF Standard 10 Determination of the Tensile Properties of Powder Metallurgy Materials

MPIF Standard 42 Determination of Density of Compacted or Sintered Powder Metallurgy Products

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

[4] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

[5] Available from Metal Powder Industries Federation (MPIF), 105 College Road East, Princeton, New Jersey 08540, http://www.mpif.org.

MPIF Standard 50 Preparing and Evaluating Metal Injection Molded Sintered/Heat Treated Tension Specimens
MPIF Standard 63 Density Determinations of MIM Components (Gas Pycnometry)
MPIF Standard 64 Terms Used in Metal Injection Molding

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 Definitions of powder metallurgy and MIM terms can be found in Terminology B243 and MPIF Standard 64. Additional descriptive information is available in the Related Material Section of Vol 02.05 of the Annual Book of ASTM Standards.

3.1.2 *absolute density, n*—the value of density used to characterize a powder material with a particular chemical composition as if it were a fully dense material, completely free of porosity.

3.1.2.1 *Discussion*—For the purposes of this specification, the skeletal density (also referred to as pycnometer density) measured on the raw material powders using the pycnometry method of Test Method B923 will be used to represent the absolute density of the particular chemical composition.

3.1.3 *debinding, n*—a step between molding and sintering where the majority of the binder used in molding is extracted by heat, solvent, a catalyst, or other techniques.

3.1.4 *feedstock, n*—in metal injection molding, a moldable mixture of metal powder and binder.

3.1.5 *feedstock batch, n*—a specified quantity of feedstock made up of the same lot of metallic powders and the same lot of binder materials mixed under the same conditions at essentially the same time.

3.1.6 *lot, n*—a specified quantity of components made up of the same batch of feedstock, debound, sintered, and post processed under the same conditions at essentially the same time.

3.1.7 *metal injection molded component, n*—product fabricated by a metal injection molding process consisting of mixing metal powders with binders to make a feedstock, introducing this feedstock into a mold by injection or other means, debinding to remove the binders, and sintering.

3.1.8 *pre-alloyed powder, n*—powder composed of two or more elements that are alloyed in the powder manufacturing process in which the particles are of the same nominal composition throughout.

3.1.9 *relative density, n*—the density ratio, often expressed as a percentage, of the density of a porous material to the absolute density of the same material, completely free of porosity.

3.1.10 *sintering*—the metallurgical bonding of particles in a MIM component resulting from a thermal treatment at a temperature below the melting point of the main constituent.

4. Ordering Information

4.1 Include with inquiries and orders for material under this specification the following information:

4.1.1 Quantity,

4.1.2 ASTM specification and date of issue,

4.1.3 Alloy 1 (low carbon) or Alloy 2 (high carbon),

4.1.4 Units to be certified—SI or inch-pound,

4.1.5 Component configuration (engineering drawing and/or 3D solid model) and dimensional requirements,

4.1.6 Condition (5.3),

4.1.7 Mechanical properties (if applicable),

4.1.8 Finish (5.3),

4.1.9 Special tests (Section 9, Section 10), if any, and

4.1.10 Other requirements.

5. Materials and Manufacture

5.1 Components conforming to this specification shall be produced by the metal injection molding process using prealloyed metal powders with major elemental composition meeting the chemical requirements of Table 1.

5.2 Post-sintering operations may be employed to achieve the desired density, shape, size, surface finish, or other component properties. The post-sintering operations to be used shall be agreed upon between the supplier and purchaser.

5.3 The condition and finish of the components shall be agreed upon between the supplier and purchaser.

6. Chemical Requirements

6.1 The components supplied under this specification shall conform to the chemical requirements in Table 1. The supplier shall not ship components with chemistry outside the requirements specified in Table 1.

6.1.1 Chemical analysis of a finished component or representative sample shall be used for reporting all chemical requirements. Any representative samples shall be produced from the same feedstock batch, debound, sintered, and post processed concurrently with the finished components they represent.

6.1.2 Requirements for the major and minor elemental constituents are listed in Table 1. Also listed are important

TABLE 1 Chemical Requirements

Element	Chemical Composition Alloy 1 (Low Carbon) (% mass/mass)		Chemical Composition Alloy 2 (High Carbon) (% mass/mass)	
	min	max	min	max
Carbon	...	0.14	0.15	0.35
Chromium	27.0	30.0	27.0	30.0
Molybdenum	5.0	7.0	5.0	7.0
Nickel	...	0.5	...	0.5
Iron	...	0.75	...	0.75
Silicon	...	1.0	...	1.0
Manganese	...	1.0	...	1.0
Tungsten	...	0.20	...	0.20
Phosphorus	...	0.020	...	0.020
Sulfur	...	0.010	...	0.010
Nitrogen	...	0.25	...	0.25
Aluminum	...	0.10	...	0.10
Titanium	...	0.10	...	0.10
Boron	...	0.010	...	0.010
Cobalt[A]	...	Balance	...	Balance

[A] Approximately equal to the difference of 100 % and the sum percentage of the other specified elements. The percentage of the cobalt difference is not required to be reported.

residual elements. The percentage of cobalt is determined by difference and need not be determined or certified.

6.1.3 All commercial metals contain small amounts of elements other than those which are specified. It is neither practical nor necessary to specify limits for unspecified elements, whether residual elements or trace elements, that can be present. The producer is permitted to analyze for unspecified elements and is permitted to report such analyses. The presence of an unspecified element and the reporting of an analysis for that element shall not be a basis for rejection.

6.1.4 Intentional elemental additions other than those specified in Table 1 are not permitted.

6.1.5 Analysis for elements not listed in Table 1 is not required to verify compliance with this specification.

6.2 *Product Analysis:*

6.2.1 Product analysis tolerances do not broaden the specified heat analysis requirements, but cover variations in the measurement of chemical content between laboratories. The product analysis tolerances shall conform to the product tolerances in Table 2.

6.2.2 The product analysis is either for the purpose of verifying the composition of the manufacturing lot or to determine variations in the composition within the lot. Acceptance or rejection of the manufacturing lot of components may be made by the purchaser on the basis of this product analysis.

6.2.3 Samples for chemical analysis shall be representative of the components being tested.

6.2.4 Product analysis outside the tolerance limits allowed in Table 2 is cause for rejection of the product. A referee analysis may be used if agreed upon by the supplier and purchaser.

6.2.5 For referee purposes, use Test Methods E354 or other analytical methods agreed upon between the purchaser and the supplier.

7. Mechanical Requirements

7.1 *Tensile Properties:*

7.1.1 The components supplied under this specification shall conform to the mechanical property requirements in Table 3.

7.1.2 Test specimens shall be taken from a MIM component if possible, or from a representative sample or molded tensile specimen. A representative sample or molded tensile specimen may only be used if the component configuration is such that a tensile specimen cannot be obtained from the component.

7.2 Representative samples or molded tensile specimens shall be produced from the same feedstock batch, debound, sintered, and post processed concurrently with the finished components that they represent.

7.2.1 Test specimens machined from components or representative samples shall be ground or machined to final dimensions in accordance Test Methods E8/E8M.

7.2.2 Alternate tensile specimen geometries may be agreed upon by the purchaser and supplier. Some examples of the configurations for molded tensile specimens are described in MPIF Standard 10 and MPIF Standard 50.

7.3 Specimens for tensile tests shall be tested in accordance with Test Methods E8/E8M.

7.4 Should any test piece not meet the specified requirements, test two additional representative test pieces, in the same manner, for each failed test piece. The lot shall be considered in compliance only if all additional test pieces meet the specified requirements.

7.5 Tensile test results for which any specimen fractures outside the gauge length shall be considered valid if both the elongation and reduction of area meet the minimum requirements specified. Refer to subsections 7.11.4 and 7.11.5 of Test Methods E8/E8M. If either the elongation or reduction of area is less than the minimum requirement, invalidate the specimen and retest. Retest one specimen for each invalidated specimen.

TABLE 2 Product Analysis Tolerance[A,B]

Element	Tolerance Under the Minimum or Over the Maximum Limit Composition (% mass/mass)[C]
Carbon	0.02
Chromium	0.30
Molybdenum	0.15
Nickel	0.05
Iron	0.03
Silicon	0.05
Manganese	0.03
Tungsten	0.04
Phosphorus	0.005
Sulfur	0.003
Nitrogen[D]	0.02
Aluminum	0.02
Titanium	0.02
Boron	0.002

[A] See Test Methods E354.
[B] See AMS 2269 for chemical check analysis limits except nitrogen.
[C] Under minimum limit not applicable for elements where only a maximum percentage is indicated.
[D] Refer to AMS 2248.

8. Dimensions and Permissible Variation

8.1 *Units of Measure:*

8.2 *Selection*—This specification requires that the purchaser selects the units (SI or inch-pound) to be used for product certification. In the absence of a stated selection of units on the purchase order, this selection may be expressed by the purchaser in several alternate forms listed in order of precedence.

TABLE 3 Mechanical Requirements

	Relative Density	
	Alloy 1 (Low Carbon)	Alloy 2 (High Carbon)
	MPa [psi]	MPA [psi]
Ultimate Tensile Strength	725 [105 000] min	825 [120 000] min
Yield Strength (0.2 % offset)	450 [65 000] min	480 [70 000] min
Elongation[A]	10 % min	10 % min
Reduction of Area	10 % min	10 % min

[A] Elongation of material 1.575 mm [0.062 in.] or greater in diameter (D) or width (W) shall be measured using a gauge length of 2 in. or 4D or 4W. The gauge length shall be reported with the test results. The method for determining elongation of material under 1.575 mm [0.062 in.] in diameter or thickness may be negotiated. Alternatively, a gauge length corresponding to ISO 6892 (5.65 times the square root of S_o, where S_o is the original cross-sectional area) when agreed upon between the supplier and purchaser.