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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 the 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 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]

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 Practice for Liquid Penetrant Examination 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)

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

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:*

[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.

3.2 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.

3.3 *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.

3.3.1 *Discussion*—For 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.

3.4 *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.

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

3.6 *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.

3.7 *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.

3.8 *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.

3.9 *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.

3.10 *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.

3.11 *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 the finished component or representative sample shall be used for reporting all chemical requirements. Any representative sample shall be produced from the same feedstock batch, debound, sintered, and post processed concurrently with the finished components that it represents.

6.1.2 Requirements for the major and minor elemental constituents are listed in Table 1. Also listed are important residual elements. The percentage of cobalt is determined by difference and need not be determined or certified.

6.1.3 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

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

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 Method 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.

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.

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 gage length of 2 in. or 4D or 4W. The gage 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 gage length corresponding to ISO 6892 (5.65 times the square root of So, where So is the original cross-sectional area) may be used when agreed upon between the supplier and purchaser.

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 tests result 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. 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.

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.

8.3 If the purchaser and supplier have a history of using specific units, these units shall continue to be certified until expressly changed by the purchaser.

8.4 In the absence of historic precedence, if the units used to define the product on the purchaser's purchase order, specification, and engineering drawing are consistent, these units shall be used by the supplier for product certification.

8.5 If the purchaser's selection of units is unclear, the units of measure shall be agreed upon between the purchaser and supplier.

8.6 *Conversion of Units*—If the supplier's test equipment does not report in the selected units, the test equipment units may be converted to the selected units for certification purposes. Accurate arithmetic conversion and proper use of significant digits should be observed when performing this conversion. ASTM SI 10 provides guidelines for the use of SI units. Annex A provides conversion tables and Annex B provides rules for conversion and significant digits.

9. Microstructure

9.1 The microstructural requirements and frequency of examinations shall be mutually agreed upon by the supplier and purchaser. Specimen preparation shall be in accordance with Guide E3 and Practice E407.

10. Density

10.1 The relative density of the finished components shall be a minimum of 98 % of the absolute density of the prealloyed metal powder lot used to make the components.

10.2 The density of the finished components shall be measured per Test Method B311, MPIF Standard 42, or MPIF Standard 63.

10.3 The absolute density of the prealloyed metal powder shall be measured in accordance with test method Test Method B923.

10.4 The component measured density shall be reported on the test report in units of g/cm^3. The component relative density shall be reported as a percent of the absolute density of the prealloyed metal powder lot used to make the component.

11. Nondestructive Examination

11.1 *Fluorescent Penetrant Examination*—When required by the purchaser, each individual component shall be subject to fluorescent penetrant examination in accordance with Test Method E165 or Practice F601, as appropriate for the surface condition of the component being tested. Acceptance criteria and a sampling plan other than 100 % inspection shall be agreed upon between the supplier and purchaser.

11.2 *Radiographic Examination*—When required by the purchaser, each individual component shall be subjected to radiographic examination in accordance with Practice F629. Acceptance criteria and a sampling plan other than 100 % inspection shall be agreed upon between the supplier and purchaser.

11.3 Other methods of nondestructive inspection may be used as agreed upon by the supplier and purchaser.

12. Significance of Numerical Limits

12.1 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.

13. Certification

13.1 The supplier shall provide a certification that the components were tested in accordance with this specification and met all requirements. A report of the test results shall be furnished to the purchaser at the time of shipment.

14. Quality Program Requirements

14.1 The supplier shall maintain a quality program as defined in ISO 9001, or similar quality program.

15. Keywords

15.1 cobalt alloy components (for surgical implants); cobalt-28chromium-6molybdenum alloy; metals (for surgical implants); metal injection molded (MIM) component; orthopedic medical components

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 *Purpose* —The purpose of this specification is to characterize the chemical, physical, mechanical, and metallurgical properties of metal injection molded, cobalt-28chromium-6molybdenum components to be used in the manufacture of surgical implants.

X1.2 *Chemistry, Process History, Microstructure, and Mechanical Properties*—The chemical composition requirements in this specification for MIM cobalt-28chromium-6molybdenum components are similar to Specification F1537 Alloys 1 and 2 for wrought cobalt-28chromium-6molybdenum and Specification F75 for cast cobalt-28chromium-6molybdenum. Neither the MIM components in this specification, nor the F75 castings benefit from the extensive microstructural refinement and directionality introduced into the F1537 wrought materials by extensive thermomechanical processing. They also do not benefit from the cold, warm, or hot worked wrought material conditions in F1537. The MIM Alloy 1 (low carbon) yield strength requirement is equal to the F75 cast material yield strength requirement. The MIM Alloy 2 (high carbon) ultimate tensile strength and yield strength requirements are between the as-cast requirements in F75 and the annealed requirements in F1537.

X1.3 *Fatigue* —It is recommended that users evaluate fatigue properties for MIM components that experience dynamic loads in service.

X1.4 *Binders* —The binders mixed with the metal powders to make the MIM feedstock are almost completely removed from the molded component during the debinding step(s) that occur prior to sintering. Any residual binder materials are decomposed to their elemental constituents during the sintering cycle. The effect of the binders on the chemical composition of the MIM components is controlled through the chemical requirements in Table 1.

X1.5 *Units of Measure—ASTM Policy*—ASTM is promoting the use of rationalized SI (metric) units in their standards. The F04.12 Committee has written this specification to facilitate the transition by the medical materials industry to SI units of measure between now and 2018. In the first phase of this transition, running to 2013, the specifications will be structured to allow the use of either SI or inch - pound units. The choice of primary units in each specification will be determined by the

industry using the specification. The change to SI units during this period may be initiated by the purchaser through his purchase documentation. In the second phase of this transition the specifications will be written with SI as the primary units. Harmonization with corresponding ISO documents will be considered when assigning the SI values.

X2. BIOCOMPATIBILITY

X2.1 The alloy composition covered by this specification has been used successfully in human implant applications in contact with soft tissue and bone for over a decade.

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 composition referred to in this standard has shown that an acceptable level of biological response can be expected, if the material is used in appropriate applications.

NOTE X2.1— MIM-specific biocompatibility references will be added upon publication of the reference.