INTERNATIONAL

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Standard Specification for Metal Injection Molded Unalloyed Titanium Components for Surgical Implant Applications[1]

This standard is issued under the fixed designation F2989; 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 three grades of metal injection molded (MIM) unalloyed titanium components in two types to be used in the manufacture of surgical implants.

1.2 The Type 1 MIM components covered by this specification may have been densified beyond their as-sintered density by post-sinter processing.

1.3 Values in either inch-pound or SI are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independent of the other. Combining values from the two systems may result in nonconformance with the specification.

1.4 *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.*

1.5 *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
B367 Specification for Titanium and Titanium Alloy Castings
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 Testing for General Industry
E407 Practice for Microetching Metals and Alloys
E539 Test Method for Analysis of Titanium Alloys by Wavelength Dispersive X-Ray Fluorescence Spectrometry
E1409 Test Method for Determination of Oxygen and Nitrogen in Titanium and Titanium Alloys by Inert Gas Fusion
E1447 Test Method for Determination of Hydrogen in Titanium and Titanium Alloys by Inert Gas Fusion Thermal Conductivity/Infrared Detection Method
E1941 Test Method for Determination of Carbon in Refractory and Reactive Metals and Their Alloys by Combustion Analysis
E2371 Test Method for Analysis of Titanium and Titanium Alloys by Direct Current Plasma and Inductively Coupled Plasma Atomic Emission Spectrometry (Performance-Based Test Methodology)
E2626 Guide for Spectrometric Analysis of Reactive and Refractory Metals (Withdrawn 2017)[3]
E2994 Test Method for Analysis of Titanium and Titanium Alloys by Spark Atomic Emission Spectrometry and Glow Discharge Atomic Emission Spectrometry (Performance-Based Method)
F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)
F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants
F629 Practice for Radiography of Cast Metallic Surgical Implants
IEEE/ASTM SI 10 American National Standard for Metric Practice

[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] The last approved version of this historical standard is referenced on www.astm.org.

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

2.2 *ISO Standards:*[4]

ISO 5832-3 Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy

ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature

ISO 9001 Quality Management Systems—Requirements

ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purpose

2.3 *Aerospace Material Specifications:*[5]

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

2.4 *MPIF Standards:*[6]

Standard 10 Determination of the Tensile Properties of Powder Metallurgy Materials

Standard 42 Determination of Density of Compacted or Sintered Powder Metallurgy Product

Standard 50 Preparing and Evaluating Metal Injection Molded Sintered/Heat Treated Tension Specimens

Standard 63 Density Determinations of MIM Components (Gas Pycnometry)

Standard 64 Terms Used in Metal Injection Molding

3. Terminology

3.1 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*.

3.2 The materials produced by means of the metal injection molding process are designated by the prefix "MIM," followed by the appropriate designation for the alloy grade. The MIM designates that it was made by metal injection molding.

3.3 *Definitions of Terms Specific to This Standard:*

3.3.1 *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.

3.3.1.1 *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 shall be used to represent the absolute density of the particular chemical composition.

3.3.2 *debinding, v*—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.

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

3.3.4 *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.

3.3.5 *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.

3.3.6 *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.

3.3.7 *near net component, n*—a component that meets dimensional tolerance as built with little post processing.

3.3.8 *net component, n*—a component that meets dimensional tolerance as built with no post processing.

3.3.9 *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.

3.3.10 *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.

3.3.11 *sintering, v*—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.

3.3.12 *Type 1, n*—a MIM component that may have been densified beyond its as-sintered density by post-sinter processing.

3.3.13 *Type 2, n*—a MIM component that shows the as-sintered density and was not densified after sintering.

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 Grade (MIM 1, MIM 2, or MIM 3),

4.1.4 Type (1 or 2),

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

4.1.6 Component configuration (engineering drawing or 3D solid model, or both) and dimensional requirements,

4.1.7 Condition (5.2),

4.1.8 Mechanical properties (if applicable),

4.1.9 Finish (5.2),

4.1.10 Special tests (Sections 9, 10, and 11), if any, and

4.1.11 Other requirements.

5. Materials and Manufacture

5.1 Components conforming to this specification shall be produced by the metal injection molding process using unalloyed 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 shall be agreed upon between the supplier and purchaser.

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

[5] Available from SAE International (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://aerospace.sae.org.

[6] Available from Metal Powder Industries Federation (MPIF), 105 College Rd. East, Princeton, NJ 08540, http://www.mpif.org.

TABLE 1 Chemical Composition

Element	Composition for both Type 1 and Type 2 Composition, % (mass/mass)		
	Grade MIM 1	Grade MIM 2	Grade MIM 3
Nitrogen, max	0.03	0.03	0.05
Carbon, max	0.08	0.08	0.08
Hydrogen, max	0.015	0.015	0.015
Iron, max	0.20	0.30	0.30
Oxygen, max	0.18	0.25	0.30
Cobalt[A]	<0.1	<0.1	<0.1
Other Elements Each,[B] max	0.10	0.10	0.10
Other Elements Total,[B] max	0.4	0.4	0.4
Titanium[C]	Balance	Balance	Balance

[A] Refer to X1.5.
[B] Other elements need not be reported unless the concentration level is greater than 0.1 % each, or 0.4 % total. Other elements may not be added intentionally. Other elements may be present in titanium or titanium alloys in small quantities and are inherent to the manufacturing process. In titanium these elements typically include aluminum, vanadium, tin, chromium, molybdenum, niobium, zirconium, hafnium, bismuth, ruthenium, palladium, yttrium, copper, silicon, tantalum, nickel, boron, manganese, and tungsten.
[C] The percentage of titanium is determined by difference and need not be determined or certified.

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.

6.2 Chemical analysis of the finished component or a 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.

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

6.2.2 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.

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

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

6.3 *Product (Check) Analysis:*

6.3.1 The product (check) analysis tolerances shall conform to the product tolerances in Table 2 per AMS 2249 and Specification B367. Product analysis tolerances do not broaden the specified heat (ladle or ingot) analysis requirements but cover variations between laboratories in the measurement of chemical content.

TABLE 2 Product (Check) Analysis Tolerance[A]

Element	Limit or Maximum of Specified Range %, (mass/mass)	Tolerance Under the Minimum or Over the Maximum Limit[B]
Nitrogen	up to 0.05	0.02
Carbon	0.10	0.02
Hydrogen	up to 0.015	0.002
Iron	up to 0.25	0.10
Iron	over 0.25	0.15
Oxygen	up to 0.20	0.02
Oxygen	over 0.20	0.03
Cobalt[C]	0.10	0.02
Other (each)	0.10	0.02

[A] See AMS 2249.
[B] Under the minimum limit is not applicable for elements where only a maximum percentage is indicated.
[C] See Specification B367.

6.3.2 Product (check) analysis limits are not for supplier's/producer's use at supplier's/producer's acceptance testing. Product analysis limits are not permitted to be applied to ladle or ingot analysis. The supplier/producer shall not ship material that is outside the limits specified in Table 1.

6.3.3 A product (check) analysis is one performed by the purchaser or supplier of the metal after it has been worked into semi-finished or finished forms or fabricated into parts, and is either for the purpose of verifying the composition of the manufacturing lot or to determine variations in the composition within the manufacturing lot. In the analysis of finished parts, these values do not apply to elements whose percentage can be varied by fabricating techniques employed (for example oxygen, nitrogen, and hydrogen) unless the sample is sufficiently large to produce a reliable result.

6.3.4 Acceptance or rejection of a heat or manufacturing lot of components may be made by the purchaser on the basis of this product (check) analysis. Product (check) 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.

6.3.5 Samples for product (check) analysis shall be representative of the component being tested. The utmost care shall be used in sampling titanium for chemical analysis because of its ability to react with elements such as oxygen, nitrogen, and hydrogen. Therefore, when cutting samples for analysis, the operation should be carried out insofar as possible in a dust-free atmosphere. Cutting tools should be clean and sharp. Samples for analysis should be stored in suitable containers.

6.3.6 For referee purposes, use Test Methods E539, E1409, E1447, E1941, E2994, and E2371 and Guide E2626 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

TABLE 3 Mechanical Requirements

	Grade MIM 1		Grade MIM 2		Grade MIM 3	
	Type 1 Densified	Type 2 Sintered	Type 1 Densified	Type 2 Sintered	Type 1 Densified	Type 2 Sintered
Ultimate Tensile Strength	405 MPa min [58 750 psi]	370 MPa min [53 650 psi]	460 MPa min [66 500 psi]	420 MPa min [61 000 psi]	545 MPa min [79 000 psi]	495 MPa min [71 800 psi]
Yield Strength (0.2 % offset)	350 MPa min [50 750 psi]	315 MPa min [45 700 psi]	380 MPa min [55 100 psi]	360 MPa min [52 200 psi]	430 MPa min [62 350 psi]	390 MPa min [56 500 psi]
Elongation[A]	24 % min	23 % min	18 % min	17 % min	12 % min	10 % min
Reduction of Area	25 % min	25 % min	20 % min	20 % min	15 % min	15 % 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 50.8 mm [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. Alternately, 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) may be used when agreed upon between the supplier and purchaser.

may only be used only if the component configuration is such that a tensile specimen cannot be obtained from the component.

7.1.3 The number of tensile tests should be agreed upon between the supplier and the 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 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 between the purchaser and supplier. Some examples of the configurations for molded tensile specimens are described in MPIF Standards 10 and 50.

7.3 Specimens for tensile tests shall be tested in accordance with Test Methods E8/E8M. Tensile properties shall be determined using a strain rate of 0.076 to 0.178 mm/mm/min [0.003 to 0.007 in./in./min] through yield and then the crosshead speed may be increased so as to produce fracture in approximately one additional minute.

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 manufacturing 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 and all other results conform to Table 3. (Refer to subsections 7.11.4 and 7.12.5 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 specimen that did not meet the minimum requirements.

8. Dimensions and Permissible Variation

8.1 *Units of Measure:*

8.1.1 *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.

8.1.2 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.

8.1.3 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.

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

8.1.5 *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. IEEE/ASTM SI 10 provides guidelines for the use of SI units. Annex A of IEEE/ASTM SI 10 provides conversion tables and Annex B of IEEE/ASTM SI 10 provides rules for conversion and significance.

9. Microstructure

9.1 Alpha case is not permitted on net components when examined on a metallurgical cross section at 100× magnification.

9.2 The alpha case requirement on near net components shall be agreed upon between supplier and purchaser.

9.3 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 component shall be a minimum of:

10.1.1 *Type 1*—98 % of the absolute density of the prealloyed metal powder lot used to make the component.

10.1.2 *Type 2*—96 % of the absolute density of the prealloyed metal powder lot used to make the component.