Designation: ~~F2885 – 11~~ F2885 – 17

Standard Specification for Metal Injection Molded Titanium-6Aluminum-4Vanadium Components for Surgical Implant Applications[1]

This standard is issued under the fixed designation F2885; 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~~ Scope*

1.1 This specification covers ~~the~~ chemical, mechanical, and metallurgical requirements for two types of metal injection molded (MIM) titanium-6aluminum-4vanadium components 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 *Units—*~~Values~~ The 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 non-conformance 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~~ safety, health, and ~~health~~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
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
E407 Practice for Microetching Metals and Alloys
E539 Test Method for Analysis of Titanium Alloys by 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]
F601 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants
F629 Practice for Radiography of Cast Metallic Surgical Implants

[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 ~~March 1, 2011~~Sept. 1, 2017. Published ~~March 2011~~October 2017. Originally approved in 2011. Last previous edition approved in 2011 as F2885 – 11. DOI: ~~10.1520/F2885-11.~~10.1520/F2885-17.

[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**

F1108 Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406)
F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)
IEEE/ASTM SI 10 American National Standard for Use of the International System of Units (SI): The Modern Metric System
2.2 *ISO Standards:*[4]
ISO 5832-3 Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy Third Edition
ISO 6892 Metallic Materials—Tensile Testing at Ambient Temperature
ISO 9001 Quality Management Systems—Requirements
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 *Definitions of Terms Specific to This Standard:*

3.2.1 *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.

[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 American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.
[6] Available from Metal Powder Industries Federation (MPIF), 105 College Rd. East, Princeton, NJ 08540, http://www.mpif.org.

3.2.1.1 *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 will be used to represent the absolute density of the particular chemical composition.

3.2.2 ~~*metal injection molded component,*~~ *debinding,* ~~*n*—~~*v*—~~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.~~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.

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

3.2.4 *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.

3.2.5 *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.

3.2.6 ~~*debinding,*~~ *metal injection molded component,* ~~*v*—~~*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.~~ 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.

~~3.2.6 *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.~~

3.2.7 *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.

~~3.2.8 *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.~~

~~3.2.8.1 *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.~~

3.2.8 *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.

3.2.9 *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.

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 Type 1 or Type 2,

4.1.4 Units to be certified—SI or Inch-Pounds,

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

4.1.6 Condition (5.2),

4.1.7 Mechanical properties (if applicable),

4.1.8 Finish (5.2),

4.1.9 Special tests (Sections 9, 10, and 11), 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 shall be agreed upon between the supplier and purchaser.

5.3 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. Supplier shall not ship components with chemistry outside the requirements specified in Table 1.~~

6.1 ~~Chemical analysis of the finished component or representative sample shall be used for reporting all chemical requirements. Any~~The components supplied under this specification shall conform to the chemical requirements in Table 1~~representative sample shall be produced from the same feedstock batch,~~. Supplier shall not ship components with chemistry outside the requirements specified in Table 1~~debound, sintered, and post processed concurrently with the finished components that it represents.~~.

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

TABLE 1 Chemical Composition

Composition for both Type 1 and Type 2 Alloys		
Element	Composition, % (Mass/Mass)	
	min	max
Nitrogen	...	0.05
Carbon	...	0.08
Hydrogen	...	0.015
Iron	...	0.30
Oxygen	...	0.20
Aluminum	5.5	6.75
Vanadium	3.5	4.5
Yttrium	...	0.005
Titanium[A]	Balance	

[A] ~~The percentage of titanium is determined by difference and need not be determined or certified.~~ Approximately equal to the difference of 100% and the sum of percentage of the other specified elements. The percentage of the Titanium difference is not required to be reported.

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.

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

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 analyses.

6.2.3 Samples for chemical analysis shall be representative of the component being tested. The utmost care must be used in sampling titanium for chemical analysis because of its affinity for elements such as oxygen, nitrogen, and hydrogen. In cutting samples for analysis, therefore, 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.

6.2.4 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 supplier and purchaser.

6.2.5 For referee purposes, use Test Methods E539, E1409, E1447, E1941, 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 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 Specimens machined from components or representative samples shall be ground, or machined to final dimensions in accordance with Test Methods E8/E8M.

7.2.2 Alternate tensile specimen geometries may be agreed upon between purchaser and supplier. Some examples of the configurations for molded tensile specimens are described in MPIF Standard 10 and Standard 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 0.003 to 0.007 mm/mm/min (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 lot shall be considered in compliance only if all additional test pieces meet the specified requirements.

TABLE 2 Product Analysis Tolerance[A]

Element	Tolerance Under the Minimum or Over the Maximum Limit Composition (% mass/mass)[B]
Nitrogen	0.02
Carbon	0.02
Hydrogen	0.002
Iron, max	0.10
Oxygen	0.02
Aluminum	0.40
Vanadium	0.15
Yttrium	0.0006

[A] See AMS 2249.

[B] Under minimum limit not applicable for elements where only a maximum percentage is indicated.