Designation: F2885 – 17 (Reapproved 2023)

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

1.1 This specification covers 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*—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 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

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

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 Reactive Metals and Reactive Metal Alloys by Inert Gas Fusion with Detection by Thermal Conductivity or Infrared Spectrometry

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

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

[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.

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.

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 *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.

3.2.3 *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 *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.

3.2.7 *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 *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.

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] 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.

[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.