



Designation: F1580-07 ~~Designation: F1580 - 12~~

## Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants<sup>1</sup>

This standard is issued under the fixed designation F1580; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

### 1. Scope\*

1.1 This specification covers the requirements for unalloyed titanium and Ti-6Al-4V alloy powders for use in fabricating coatings on titanium alloy implants.

1.2 Powders covered under this specification may be used to form coatings by sintering or thermal spraying techniques.

1.3 This specification covers powder requirements only. It does not address properties of the coatings formed from them.

~~1.4 Finely divided titanium powder may be considered pyrophoric and should be handled in accordance with the appropriate guidelines.~~

1.4 Finely divided titanium powder may be considered pyrophoric and should be handled in accordance with the appropriate guidelines.

1.5 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

### 2. Referenced Documents

#### 2.1 ASTM Standards:<sup>2</sup>

B214 Test Method for Sieve Analysis of Metal Powders

B215 Practices for Sampling Metal Powders

B299 Specification for Titanium Sponge

E11 Specification for Woven Wire Test Sieve Cloth and Test Sieves

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

E2371 Test Method for Analysis of Titanium and Titanium Alloys by Atomic Emission Plasma Spectrometry

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700) F981

F981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone

F1472 Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400)

#### 2.2 ISO Standards:<sup>3</sup>

ISO 9001 Quality Management System Requirements

#### 2.3 American Society for Quality (ASQ) Standards:

ASQC1 General Requirements for a Quality Program

#### ~~2.4 Aerospace Material Specifications:<sup>4</sup>~~

AMS 2249 Chemical Check Analysis Limits, Titanium and Titanium Alloys

AMS 4998 Powder, 6Al-4V

### 3. Significance and Use

3.1 Coatings formed from metallic powders have become widely used as a means of improving tissue attachment to implants. Such coatings have also been demonstrated to improve bonding of acrylic cement to prostheses. This specification addresses the

<sup>1</sup> This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is under the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

Current edition approved December 1, 2007-2012. Published December 2007-March 2012. Originally approved in 1995. Last previous edition approved in 2004-2007 as F1580 - 04.7. DOI: 10.1520/F1580-07.10.1520/F1580-12.

<sup>2</sup> 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.

<sup>3</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

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

<sup>4</sup> Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.

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

special requirements of the metal powders used to form these coatings.

#### 4. Methods of Manufacture

4.1 Powders may be manufactured by the plasma rotating electrode process, inert gas atomization, hydride-dehydride, or other method capable of producing powder meeting the requirements of this specification.

#### 5. Chemical Requirements

5.1 The chemical analysis of the powder shall conform to the requirements specified in Table 1.

5.1.1 Requirements for the major and minor elemental constituents for unalloyed titanium and Ti-6Al-4V alloy powders are listed in Table 1. Also listed are all important residual elements. Analysis for elements not listed in Table 1 is not required to verify compliance with this specification.

5.2 The product analysis tolerance shall conform to the requirements set forth in Table 2.

~~5.3 For referee purposes, Test Method~~

5.3 For referee purposes, Test Method E2371 shall be used.

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

5.5 For powder that includes particle size fractions finer than 200 mesh (74  $\mu\text{m}$ ), the oxygen content limits shall be agreed upon between buyer and seller.

#### 6. Particle Size

6.1 Powder shall be sieved to the customer's requirements with stainless steel screens conforming to Specification E11. Analysis of sieved powder for conformance to the customer's particle size range requirements shall be in accordance with Test Method B214.

#### 7. Cleanliness

7.1 Powder shall be handled at all times so as to ensure freedom from contamination with nonmetallic materials or other metal alloy powders or both.

7.2 Powder cleanliness shall be determined by examining a representative sample, per Practices B215 or as agreed upon between buyer and seller, comprising at least 1 in.<sup>2</sup> (6.45 cm<sup>2</sup>) of a closely packed mono-layer of powder per lot at 20 $\times$  magnification. No foreign material shall be visible under these conditions.

#### 8. Significance of Numerical Limits

8.1 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.

**TABLE 1 Chemical Requirements**

| Element | Unalloyed Ti Powder <sup>A</sup> |      | Ti Sponge Powder <sup>B</sup> |                   | Ti-6Al-4V Powder <sup>C</sup> |                    |
|---------|----------------------------------|------|-------------------------------|-------------------|-------------------------------|--------------------|
|         | % (mass/mass)                    |      | % (mass/mass)                 |                   | % (mass/mass)                 |                    |
|         | Min                              | Max  | Min                           | Max               | Min                           | Max                |
| Al      |                                  |      |                               | 0.05              | 5.50                          | 6.75               |
| V       |                                  |      |                               |                   | 3.50                          | 4.50               |
| O       |                                  | 0.40 |                               | 0.40 <sup>D</sup> |                               | 0.20               |
| Fe      |                                  | 0.50 |                               | 0.15              |                               | 0.30               |
| C       |                                  | 0.08 |                               | 0.03              |                               | 0.08               |
| H       |                                  | 0.05 |                               | 0.03              |                               | 0.015              |
| N       |                                  | 0.05 |                               | 0.02              |                               | 0.05               |
| Cu      |                                  |      |                               |                   |                               | 0.10               |
| Sn      |                                  |      |                               |                   |                               | 0.10               |
| Si      |                                  |      |                               | 0.04              |                               |                    |
| Cl      |                                  |      |                               | 0.20 <sup>E</sup> |                               |                    |
| Na      |                                  |      |                               | <sub>F</sub>      |                               |                    |
| Y       |                                  |      |                               |                   |                               | 0.005 <sup>C</sup> |
| Ti      | balance <sup>G</sup>             |      | balance <sup>G</sup>          |                   | balance <sup>G</sup>          |                    |

<sup>A</sup> Chemistry per Specification F67 except hydrogen.

<sup>B</sup> Chemistry per Specification B299, general purpose grade.

<sup>C</sup> Chemistry per Specification F1472.

<sup>D</sup> Oxygen per Specification B299 is 0.15 %. This level is reasonable for sponge product but not for powder because of the increased surface area of small particle powder product.

<sup>E</sup> Lower maximum chlorine content may be agreed upon between buyer purchaser and seller supplier.

<sup>F</sup> Sodium or magnesium, 0.50 maximum.

<sup>G</sup> The percentage of titanium is determined by difference and need not be measured.