



Designation: **F603–12 F603 – 12 (Reapproved 2016)**

## Standard Specification for High-Purity Dense Aluminum Oxide for Medical Application<sup>1</sup>

This standard is issued under the fixed designation F603; 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 material requirements for high-purity, dense aluminum oxide for load-bearing surgical implant applications.

1.2 This specification does not cover finished parts (for example, femoral heads, acetabular inserts, dental implants and the like). It is intended as a qualification of the material as delivered to the parts manufacturer.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

### 2. Referenced Documents

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

**C373** Test Methods for Determination of Water Absorption and Associated Properties by Vacuum Method for Pressed Ceramic Tiles and Glass Tiles and Boil Method for Extruded Ceramic Tiles and Non-tile Fired Ceramic Whiteware Products

**C1161** Test Method for Flexural Strength of Advanced Ceramics at Ambient Temperature

**C1198** Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Sonic Resonance

**C1239** Practice for Reporting Uniaxial Strength Data and Estimating Weibull Distribution Parameters for Advanced Ceramics

**C1259** Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Impulse Excitation of Vibration

**C1327** Test Method for Vickers Indentation Hardness of Advanced Ceramics

**E112** Test Methods for Determining Average Grain Size

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

2.2 *American Society for Quality Control Standard*:<sup>3</sup>

**ASQ C1** Specification of General Requirements for a Quality Program

2.3 *ISO Standard*:<sup>4</sup>

**ISO 6474** Implants for Surgery—Ceramic Materials Based on Alumina

### 3. Chemical Requirements

3.1 The chemical composition shall be as follows shown in **Table 1**, (measured by ICP-AES, XRF, or mass spectroscopy):

### 4. Physical Requirements

4.1 The minimum bulk density shall be  $(3.94 \pm 0.01)$  g/cm<sup>3</sup> as determined by Test Method **C373** as applied with the following modifications.

4.1.1 Weight determination, 3.1 and 5.1 of Test Method **C373** shall be made to the nearest 0.001 g.

4.1.2 The calculation of bulk density in 12.1 of Test Method **C373** shall be calculated as follows:

$$B = (D \cdot d) / (M - S) \quad (1)$$

<sup>1</sup> This specification is under the jurisdiction of ASTM Committee **F04** on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee **F04.13** on Ceramic Materials.

Current edition approved Jan. 1, 2012/Oct. 1, 2016, Published January 2012/October 2016. Originally approved in 1983. Last previous edition approved in 2009/2012 as F603–000, with was withdrawn in March 2009 and reinstated in January 2012. DOI: 10.1520/F0603-12; – 12. DOI: 10.1520/F0603-12R16.

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

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

**TABLE 1 Chemical Properties**

Oxide	Weight Percent
Al <sub>2</sub> O <sub>3</sub>	≥ 99.5
MgO	≤ 0.5
Other Oxides	≤ 0.1

where:

- B** = bulk density (g/cm<sup>3</sup>),  
**D** = dry weight (g),  
**M** = saturated weight (g),  
**S** = suspended weight (g), and  
**d** = density of water at the temperature when measurement is taken.

where:

- B** = bulk density (g/cm<sup>3</sup>),  
**D** = dry weight (g),  
**M** = saturated weight (g),  
**S** = suspended weight (g), and  
**d** = density of water at the temperature when measurement is taken.

4.2 The median grain size shall be 4.5 μm or less, in accordance with Section 10 of Test Methods E112.

## 5. Mechanical Requirements (Table 2)

5.1 The average room temperature flexural strength for 10 samples shall be no less than 400 MPa (58 000 psi) by ~~four-point~~ four-point bend in accordance with Test Method C1161, test configuration B. The specimen shall be prepared in accordance with Test Method C1161, 7.2.4, to a 500 grit finish.

5.2 The room temperature elastic modulus shall be measured in accordance with Test Method C1239 or Test Method C1198.

5.3 The minimum Vickers Hardness values for a 1 kg load shall be 18 GPa (2.56 × 10<sup>6</sup> psi) in accordance with Test Method C1327.

5.4 The minimum Weibull modulus for 30 samples as calculated using Test Method C1239 shall be no less than 8 by ~~four-point~~ four-point bend in accordance with Test Method C1161, test configuration B. The specimens shall be prepared in accordance with Test Method C1161, 7.2.4, to a 500 grit finish.

## 6. Test Specimen Fabrication

6.1 Specific test specimens shall be prepared from the same batch of material and by the same processes as those employed in fabricating the ceramic implant device.

## 7. Quality Program Requirements

7.1 The producer shall maintain a quality program, such as the program defined in ASQ C1.

7.2 The manufacturer of surgical implants shall be assured of the producer's quality program for conformance to the intent of ASQ C1 or any other recognized program.

**TABLE 2 Mechanical Properties**

Compressive Strength GPa (ksi)	4
Expected Minimum	(580)
Average Flexural Strength MPa (psi)	400
Required Minimum	(58 000)
Elastic Modulus GPa (ksi)	380
Required Minimum	(55 100)
Vickers Hardness GPa (ksi)	18
Required Minimum	(2.56 × 10 <sup>6</sup> )
Weibull Modulus	8
Required Minimum	