



Designation: F603 – 12 (Reapproved 2016)

Standard Specification for High-Purity Dense Aluminum Oxide for Medical Application¹

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 (ϵ) 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*:²

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*:³

ASQ C1 Specification of General Requirements for a Quality Program

2.3 *ISO Standard*:⁴

ISO 6474 Implants for Surgery—Ceramic Materials Based on Alumina

3. Chemical Requirements

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

4. Physical Requirements

4.1 The minimum bulk density shall be $(3.94 \pm 0.01) \text{ g/cm}^3$ 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:

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

where:

B = bulk density (g/cm^3),

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 bend in accordance with Test Method **C1161**, test

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 F04.13 on Ceramic Materials.

Current edition approved Oct. 1, 2016. Published October 2016. Originally approved in 1983. Last previous edition approved in 2012 as F603 – 12. DOI: 10.1520/F0603-12R16.

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

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