



Designation: F 603 – 00

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

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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.

2. Referenced Documents

2.1 ASTM Standards:

C 373 Test Method for Water Absorption, Bulk Density, Apparent Porosity, and Apparent Specific Gravity of Fired Whiteware Products²

C 1161 Test Method for Flexural Strength of Advanced Ceramics at Ambient Temperature³

C 1198 Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Sonic Resonance³

C 1239 Standard Practice for Reporting Uniaxial Strength Data and Estimating Weibull Distribution Parameters for Advanced Ceramics³

C 1259 Test Method for Dynamic Young's Modulus, Shear Modulus and Poisson's Ratio for Advanced Ceramics by Impulse Excitation of Vibration³

C 1327 Standard Test Method for Vickers Indentation Hardness of Advanced Ceramics³

E 112 Methods for Determining Average Grain Size⁴

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone⁵

2.2 American Society for Quality Control:

C 1 Specification of General Requirements for a Quality Program⁶

2.3 ISO:

ISO 6474:1994 Implants for Surgery - Ceramic Materials Based on Alumina⁷

3. Chemical Requirements

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

4. Physical Requirements

4.1 The minimum bulk density shall be $(3.94 \pm .01) \text{ g/cm}^3$ as determined by Test Method C 373 as applied with the following modifications.

4.1.1 Weight determination, 3.1 and 5.1 of C 373 shall be made to the nearest 0.001 g.

4.1.2 The calculation of bulk density in 12.1 of C 373 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)

d = Density of water at the temperature when measurement is taken.

4.2 The median grain size shall be $4.5 \mu\text{m}$ or less, in accordance with Section 10 of Methods E 112.

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 C 1161 test configuration B. The specimen shall be prepared in accordance with Test Method C 1161 7.2.4 to a 500 grit finish.

¹ This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices, and is the direct responsibility of Subcommittee F04.13 on Ceramic Materials.

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² Annual Book of ASTM Standards, Vol 15.02.

³ Annual Book of ASTM Standards, Vol 15.01.

⁴ Annual Book of ASTM Standards, Vol 03.01.

⁵ Annual Book of ASTM Standards, Vol 13.01.

⁶ Available from American Society for Quality Control, 161 West Wisconsin Ave., Milwaukee, WI 52303.

⁷ Available from the American National Standards Institute 11 West 42nd St. 13th Floor, New York, NY 10036.