



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. No other units of measurement are included in this standard.

2. Referenced Documents

2.1 ASTM Standards:²

C373 Test Method for Water Absorption, Bulk Density, Apparent Porosity, and Apparent Specific Gravity of Fired 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 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 follows in **Table 1**, (measured by ICP-AES, XRF, or mass spectroscopy):

4. Physical Requirements

4.1 The minimum bulk density shall be $(3.94 \pm 0.01) \text{ g/cm}^3$ 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 configuration B. The specimen shall be prepared in accordance with Test Method **C1161**, 7.2.4, to a 500 grit finish.

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.

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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 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>.

TABLE 1 Chemical Properties

Oxide	Weight Percent
Al ₂ O ₃	≥ 99.5
MgO	≤ 0.5
Other Oxides	≤ 0.1

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 ⁶)
Weibull Modulus	8
Required Minimum	

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 × 10⁶ 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 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.

8. Keywords

8.1 advanced ceramics; alumina; aluminum oxide; ceramic; surgical implant

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE

X1.1 This standard is needed to ensure a high quality material for use in biological applications. The chemical, physical and mechanical requirements serve as criteria for a high-purity, consistent product that can be implanted in the

body. These requirements provide specifications for biocompatible grades of aluminum oxide for use in the physiological environments.

X2. BIOCOMPATIBILITY

X2.1 No known surgical implant has ever been shown to be completely free of adverse reactions in the human body. However, long term clinical experience has shown an acceptable level of biological response can be expected, if the material is used in appropriate applications.

X2.2 Aluminum oxide in accordance with Section 3 has been demonstrated to exhibit a well characterized biological response which is less than that exhibited by the reference materials cited and tested in Practice F981 or equivalent (Refs 1-6).

REFERENCES

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- (5) Richardson, W. C., et al., "Soft Tissue Response to a Series of Dense Ceramic Materials and Two Clinically Used Biomaterials," *Publications 415*, National Bureau of Standards, 1974, pp. 37–44.
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- (8) Miyayama, M., et al., *Engineering Properties of Single Oxides*, Engineering Materials Handbook, Chapter 4: Ceramics and Glasses ASM, Int'l (1991) pp 748–757.

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