Designation: F 603 – 00

Standard Specification for High-Purity Dense Aluminum Oxide for Medical Application[1]

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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 Products[2]

C 1161 Test Method for Flexural Strength of Advanced Ceramics at Ambient Temperature[3]

C 1198 Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Sonic Resonance[3]

C 1239 Standard Practice for Reporting Uniaxial Strength Data and Estimating Weibull Distribution Parameters for Advanced Ceramics[3]

C 1259 Test Method for Dynamic Young's Modulus, Shear Modulus and Poisson's Ratio for Advanced Ceramics by Impulse Excitation of Vibration[3]

C 1327 Standard Test Method for Vickers Indentation Hardness of Advanced Ceramics[3]

E 112 Methods for Determining Average Grain Size[4]

F 981 Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone[5]

2.2 *American Society for Quality Control:*

C 1 Specification of General Requirements for a Quality Program[6]

2.3 *ISO:*

ISO 6474:1994 Implants for Surgery - Ceramic Materials Based on Alumina[7]

3. Chemical Requirements

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

4. Physical Requirements

4.1 The minimum bulk density shall be (3.94 ± .01) 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 µm 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.

5.2 The room temperature elastic modulus shall be measured in accordance with C 1259 or C 1198.

5.3 The minimum Vickers Hardness values for a 1 Kg load shall be 18 GPa (2.56 × 10^6 psi) in accordance with Test Method C 1327.

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[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.

TABLE 1 Chemical Properties

Oxide	Weight Percent
Al_2O_3	≥ 99.5
MgO	≤ 0.5
Other Oxides	≤ 0.1

TABLE 2 Mechanical Properties

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

5.4 The minimum Weibull modulus for 30 samples as calculated using C 1239 shall be no less than 8 by four point bend in accordance with Test Method C 1161, test configuration B. The specimens shall be prepared in accordance with Test Method C 1161 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 ASQC C 1.

7.2 The manufacturer of surgical implants shall be assured of the producer's quality program for conformance to the intent of ASQC C 1 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 F 981 or equivalent (Refs **1-6**).

REFERENCES

(**1**) Hentrich, R.L., Graves, G.A., Stein, H.G. and Bajpai, P.K., "An Evaluation of Inert and Resorbable Ceramics for Future Clinical Orthopaedic Applications," Journal of Biomedical Materials Research, Vol. 5, 1971, p.25.

(**2**) Griss, P., et al.," Experimentelle Untersuchung zur Gewebsverträglichkeit oxidkeramischer (Al_2O_3) Abriebteilchen," Archiv für Orthopaedische und Unfallchirurgie, Vol. 76, 1973, pp. 270-279.

(**3**) Griss, P., et al., "Biological Activity and Histocompatibility of Dense Al_2O_3/MgO Ceramic Implants in Rats," Journal of Biomedical Materials Research Symposium No. 4, 1973, pp. 453-462.

(**4**) Griss, P., et al., "Experimental Analysis of Ceramic-Tissue Interactions: A Morphologic, Fluorescence-Optic and Radiographic Study on Dense Aluminum Oxide in Various Animals," Journal of Biomedical Materials Research, Symposium No. 5, Part 1, 1974, pp. 39-48.

(**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.

(**6**) Wolfson, S.H., et al., "Load-Bearing Capacity of Functioning Alumina Dental Endosseous Implants," Journal of Dental Research, Vol. 44, No. 1, 1976, pp. 22-29.

(**7**) Dörre, E and Hübner, H., *Alumina: Processing, Properties and Applications*, Springer-Verlag, New York (1984) Chapter 3, pp. 74-187.

(**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.