Designation: F603 – 12 (Reapproved 2020)

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

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.

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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 spectrocopy):

4. Physical Requirements

4.1 The minimum bulk density shall be (3.94 ± 0.01) 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.

[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 Aug. 1, 2020. Published August 2020. Originally approved in 1983. Last previous edition approved in 2016 as F603 – 12 (2016). DOI: 10.1520/F0603-12R20.

[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_2O_3	≥ 99.5
MgO	≤ 0.5
Other Oxides	≤ 0.1

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.

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

5.2 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 (2.56×10^6 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

(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.