Designation: F 603 – 83 (Reapproved 1995)

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

This standard is issued under the fixed designation F 603; 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 surgical implant applications.

1.2 The values stated in SI units are to be regarded as the standard.

1.3 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 361 or equivalent **(1-6)**.[2]

2. Referenced Documents

2.1 *ASTM Standards:*

C 20 Test Methods for Apparent Porosity, Water Absorption, Apparent Specific Gravity, and Bulk Density of Burned Refractory Brick and Shapes by Boiling Water[3]

C 573 Methods for Chemical Analysis of Fireclay and High-Alumina Refractories[4]

C 674 Test Methods for Flexural Properties of Ceramic Whiteware Materials[5]

E 112 Test Methods for Determining Average Grain Size[6]

F 361 Practice for Assessment of Compatibility of Metallic Materials for Surgical Implants with Respect to Effect of Materials on Tissue[7]

2.2 *American Society for Quality Control*[8]

C 1 Specification of General Requirements for a Quality Program

3. Chemical Requirements

3.1 The chemical analysis shall indicate an aluminum oxide (Al_2O_3) content of 99.5 % or greater.

3.2 The combined total of silicon dioxide (SiO_2) and alkali oxides shall be no greater than 0.1 %.

3.3 For referee purposes, Methods C 573 shall be used.

4. Physical Requirements

4.1 The minimum bulk density shall be 3.90 g/cm^3 as determined by Test Methods C 20 as applied with the following modifications:

4.1.1 The sample volume in 2.1 of Test Methods C 20 shall be approximately 300 mm^3 or greater.

4.1.2 Weight determinations in 3.1 and 5.1 of Test Methods C 20 shall be made to the nearest 0.0005 g.

4.1.3 The calculation of bulk density in 12.1 of Test Methods C 20 shall be calculated as follows:

$$B = D/(D - W) \quad (1)$$

where:

B = bulk density,
D = dry weight, and
W = suspended weight.

4.2 The average grain size shall be 7 µm or less, in accordance with Section 10 of Test Methods E 112.

5. Mechanical Requirements

5.1 The minimum room temperature flexural strength shall be 400 MPa (58 000 psi) in accordance with Test Methods C 674 as applied with the following modification:

5.1.1 The specimen geometry in 5.2 of Test Methods C 674 shall be rectangular, approximately 5 by 5 mm in cross section and at least 35 mm in length.

5.2 The minimum room temperature elastic modulus shall be 380 000 MPa (55.1×10^6 psi) in accordance with Test Methods C 674 except that the specimen geometry shall be modified as in 5.1.1.

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.

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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] The boldface numbers in parentheses refer to the list of references appended to this specification.

[3] *Annual Book of ASTM Standards*, Vol 15.01.

[4] *Annual Book of ASTM Standards*, Vol 03.06.

[5] *Annual Book of ASTM Standards*, Vol 15.02.

[6] *Annual Book of ASTM Standards*, Vol 03.01.

[7] *Discontinued*—see *1986 Annual Book of ASTM Standards*, Vol 13.01.

[8] Available from American Society for Quality Control, 161 West Wisconsin Ave., Milwaukee, WI 53203.

7. Quality Program Requirements

7.1 The producer shall maintain a quality program, such as the program defined in ASQC C1.

7.2 The manufacturer of surgical implants shall be assured of the producers quality program for conformance to the intent of ASQC C1 or any other recognized program.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 This standard is needed to assure 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.

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 Gewebsvertraglickeit oxidkeramischer (Al_2O_3) Abriebteilchen," *Archiv Fuer 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, Fluorescense-Optic and Radiographic Study on Dense Aluminum Oxide in Various Animals," *Journal of Biomedical Materials Research*, Symposium No. 5, Part I, 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," *Publication 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 55, No. 1, 1976, pp. 22–29.