



Designation: F 603 – 83 (Reapproved 1995)

# Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application<sup>1</sup>

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 ( $\epsilon$ ) 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).<sup>2</sup>

## 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<sup>3</sup>

C 573 Methods for Chemical Analysis of Fireclay and High-Alumina Refractories<sup>4</sup>

C 674 Test Methods for Flexural Properties of Ceramic Whiteware Materials<sup>5</sup>

E 112 Test Methods for Determining Average Grain Size<sup>6</sup>

F 361 Practice for Assessment of Compatibility of Metallic Materials for Surgical Implants with Respect to Effect of Materials on Tissue<sup>7</sup>

### 2.2 American Society for Quality Control<sup>8</sup>

C 1 Specification of General Requirements for a Quality Program

## 3. Chemical Requirements

3.1 The chemical analysis shall indicate an aluminum oxide

(Al<sub>2</sub>O<sub>3</sub>) content of 99.5 % or greater.

3.2 The combined total of silicon dioxide (SiO<sub>2</sub>) 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<sup>3</sup> 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<sup>3</sup> 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  $\mu$ m 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  $\times$  10<sup>6</sup> 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.

<sup>1</sup> 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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<sup>2</sup> The boldface numbers in parentheses refer to the list of references appended to this specification.

<sup>3</sup> *Annual Book of ASTM Standards*, Vol 15.01.

<sup>4</sup> *Annual Book of ASTM Standards*, Vol 03.06.

<sup>5</sup> *Annual Book of ASTM Standards*, Vol 15.02.

<sup>6</sup> *Annual Book of ASTM Standards*, Vol 03.01.

<sup>7</sup> *Discontinued*—see 1986 *Annual Book of ASTM Standards*, Vol 13.01.

<sup>8</sup> Available from American Society for Quality Control, 161 West Wisconsin Ave., Milwaukee, WI 53203.