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Standard Specification for Glass and Glass Ceramic Biomaterials for Implantation[1]

This standard is issued under the fixed designation F 1538; 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.

ϵ^1 NOTE—Mercury warning was editorially added in April 2008.

1. Scope

1.1 This specification covers the material requirements and characterization techniques for glass and glass-ceramic biomaterials intended for use as bulk porous or powdered surgical implants, or as coatings on surgical devices, but not including drug delivery systems.

1.2 The biological response to glass and glass-ceramic biomaterials in bone and soft tissue has been demonstrated in clinical use (~~**1-9**~~**1-12**)[2] ~~and laboratory studies **10-14**.~~ and laboratory studies (**13-17**).

1.3 This specification excludes synthetic hydroxylapatite, hydroxylapatite coatings, aluminum oxide ceramics, alpha- and beta-tricalcium phosphate, and whitlockite.

1.4 **Warning—**Mercury has been designated by EPA and many state agencies as a hazardous material that can cause central nervous system, kidney, and liver damage. Mercury, or its vapor, may be hazardous to health and corrosive to materials. Caution should be taken when handling mercury and mercury-containing products. See the applicable product Material Safety Data Sheet (MSDS) for details and EPA's website (http://www.epa.gov/mercury/faq.htm) for additional information. Users should be aware that selling mercury or mercury-containing products, or both, in your state may be prohibited by state law.

2. Referenced Documents

2.1 *ASTM Standards:*[3]

C 158~~Method for Flexural Testing of Glass (Determination of Modulus of Rupture)~~ Test Methods for Strength of Glass by Flexure (Determination of Modulus of Rupture)

C 169 Test Method for Chemical Analysis of Soda-Lime and Borosilicate Glass

C623~~Test Method for Young's Modulus, Shear Modulus, and Poisson's Ratio for Glass and Glass-Ceramics by Resonance~~[3] 373 Test Method for Water Absorption, Bulk Density, Apparent Porosity, and Apparent Specific Gravity of Fired Whiteware Products

C 623 Test Method for Young's Modulus, Shear Modulus, and Poisson's Ratio for Glass and Glass-Ceramics by Resonance

C 633 Test Method for Adhesion or Cohesive Strength of ~~Flame-Sprayed~~ Thermal Sprayed Coatings

C 693 Test Method for Density of Glass by Buoyancy

C 729 Test Method for Density of Glass by the Sink-Float Comparator

C 730~~Test Method for Knoop Indentation Hardness of Glass~~[3]

C958~~Method for Determination of Particle Size Distribution of Alumina or Quartz by X-Ray Monitoring of Gravity Sedimentation~~[3] Test Method for Knoop Indentation Hardness of Glass

C 958 Test Method for Particle Size Distribution of Alumina or Quartz by X-Ray Monitoring of Gravity Sedimentation

C 1069~~Method for Specific Surface Area of Alumina or Quartz by Nitrogen Adsorption~~[3]

C1070~~Test Method for Determining Particle Size Distribution of Alumina or Quartz by Laser Light Scattering~~[3] Test Method for Specific Surface Area of Alumina or Quartz by Nitrogen Adsorption

C 1070 Test Method for Determining Particle Size Distribution of Alumina or Quartz by Laser Light Scattering

E 228 Test Method for Linear Thermal Expansion of Solid Materials with a Vitreous Silica Dilatometer

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

~~[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 at the end of this specification.

[3] 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* ~~, Vol 15.02.~~volume information, refer to the standard's Document Summary page on the ASTM website.

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

2.2 *Code of Federal Regulations:*[4]

Title 21, Part 820

2.3 *United States Pharmacopoeia:*[5]

Lead <252>

Mercury <261>

Arsenic <211>

~~Heavy Metals <231>Method found in Annual Book of ASTM Standards, vol 13.01.~~

~~2.4 *U.S. Geological Survey Method:*[7]~~

~~(7) Cadmium~~

Heavy Metals <231> Method I

2.4 *U.S. Geological Survey Method:*[6]

Cadmium

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *bioactive glass*—~~an amorphous solid that is not intrinsically adhesive and that is capable of forming a cohesive bond with both hard and soft tissue when exposed to appropriate in vivo or in vitro environments, such as simulated body fluid or tris-hydroxymethylaminomethane buffer, by developing a surface layer of hydroxycarbonate apatite by release of ionic species from the bulk material.~~ —an amorphous silicate-based solid that is not intrinsically adhesive and that is capable of forming a cohesive bond with both hard and soft tissue when implanted, and will develop a hydroxycarbonate apatite layer when exposed to appropriate *in vitro* environments, such as simulated body fluid or tris-hydroxymethylaminomethane buffer.

3.1.2 *bioactive glass-ceramic*—~~an amorphous-derived crystalline solid that is not intrinsically adhesive and that is capable of forming a cohesive bond with bone and soft tissue when exposed to appropriate in vivo or in vitro environments, such as simulated body fluid or tris-hydroxymethylaminomethane buffer, by developing a surface layer of hydroxycarbonate apatite by release of ionic species from the bulk material.~~ —an amorphous-derived crystalline silicate-based solid that is not intrinsically adhesive and that is capable of forming a cohesive bond with bone and soft tissue when implanted, and will develop a hydroxycarbonate apatite layer when exposed to appropriate *in vitro* environments, such as simulated body fluid or tris-hydroxymethylaminomethane buffer.

3.1.3 *bulk material*—intended to describe a unit material used as a load bearing implant.

3.1.4 *coating*—intended to describe a surface layer that is relatively thin compared to the overall dimensions of the prosthetic part that has been coated.

3.1.5 *glass biomaterial*—any one of a number of compositions of amorphous inorganic solids that are used as implant materials for various medical or dental uses, or both.

3.1.6 *glass-ceramic biomaterials*—any one of a number of compositions of an amorphous-derived crystalline solid that is used as an implantable biomaterial for medical or dental use, or both.

3.1.7 *particulate material*—intended to describe several pieces (usually small size) used together within an implant construct.

4. Chemical Requirements

4.1 Bulk compositions shall be tested using Test Method C 169.

4.2 The concentration of ~~heavy metals~~trace element levels in the bioactive glass and glass-ceramics shall be limited as follows:

Element	ppm, max
~~As~~	~~3~~
Arsenic (As)	3
~~Cd~~	~~5~~
Cadmium (Cd)	5
~~Hg~~	~~5~~
Mercury (Hg)	5
~~Pb~~	~~30~~
Lead (Pb)	30
total heavy metals (as lead)	50

~~For referee purposes, the methods listed in 2.2 and~~

~~[4] Annual Book of ASTM Standards, Vol 02.05.~~

[4] Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.

~~[5] Annual Book of ASTM Standards, Vols 03.01 and 14.02.~~

[5] Available from United Stated Pharmacopia, 12601 Twinbrook Parkway, Rockville, MD 20852.

~~[6] Annual Book of ASTM Standards, Vol 13.01.~~

[6] Crock, J.G., Felichte, F.E., Briggs, P.H., "Determination of Elements in National Bureau of Standards Geological Reference Materials SRM 278 Obsidian and SRM 688 Basalt by Inductively Coupled Plasma-Atomic Emission Spectrometry," *Geostandards Newsletter*, Vol 7, 1983, pp. 335-340.