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Standard Specification for Implantable Breast Prostheses[1]

This standard is issued under the fixed designation F703; 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 requirements for silicone gel-filled and saline-inflatable silicone gel-filled implantable breast prostheses intended for use in surgical reconstruction, augmentation, or replacement of the breast.

1.2 *Limitations*—This specification does not cover custom fabricated implantable breast prostheses.

1.3 Single-use saline-inflatable, smooth and textured silicone shell implantable breast prostheses are addressed in Specification F2051.

1.4 The values stated in SI units are to be regarded as the standard. The inch-pound units given in parentheses are for information only.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *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]

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D1349 Practice for Rubber—Standard Conditions for Testing

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)[3]

F2038 Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part I—Formulations and Uncured Materials

F2042 Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II—Crosslinking and Fabrication

F2051 Specification for Implantable Saline Filled Breast Prosthesis

2.2 *Other Documents:*

Guidance for Industry and FDA Staff Saline, Silicone Gel, and Alternative Breast Implants, November 17, 2006[4]

ISO/AAMI/ANSI 10993-1 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing[5]

3. Terminology

3.1 *Definitions:*

3.1.1 *barrier coat, n*—a silicone elastomer layer that is part of the shell of a silicone gel implantable breast prosthesis that retards silicone bleed.

3.1.2 *fixation site, n*—an area of the shell of an implantable breast prosthesis containing material that allows tissue ingrowth.

3.1.3 *fused or adhered joints (seams), n*—sites in the shell or other parts of an implantable breast prosthesis where materials have been joined (fused or bonded) together, with or without an adhesive, as part of the manufacturing process.

3.1.4 *gel bleed, n*—diffusion of liquid silicone components of silicone gel through the shell of an implantable breast prosthesis.

3.1.5 *gel-filled breast prosthesis, n*—implantable breast prosthesis designed and provided with a pre-filled, fixed volume of silicone gel.

3.1.5.1 *Type I breast prosthesis, n*—implantable breast prosthesis containing a single lumen containing a fixed amount of

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[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] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from U.S. Department of Health and Human Services, Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857, http://www.fda.gov/cdrh/ode/guidance/1239.

[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

silicone gel.

(*1*) *Discussion*—The lumen of a Type I breast prosthesis is not accessible for volume adjustments of any kind.

3.1.5.2 *Type II breast prosthesis, n*—implantable breast prosthesis comprised of two complete lumens, one inside the other.

(*1*) *Discussion*—The inner lumen of a Type II implantable breast prosthesis contains a fixed amount of silicone gel and is not accessible for volume adjustments of any kind. The outer lumen is provided with a valve to facilitate filling the void between the inner and outer lumens with saline to adjust the total volume of the prosthesis at the time of use. The valve system may also be designed to facilitate postoperative saline volume adjustment by following the instructions provided in the product literature.

3.1.5.3 *Type III breast prosthesis, n*—implantable breast prosthesis comprised of two complete lumens, one inside the other.

(*1*) *Discussion*—The area between the inner and outer lumens contains a fixed amount of silicone gel and is not accessible for volume adjustments of any kind. The inner lumen is contained within the silicone gel contained in the outer lumen and has a valve system to facilitate filling the inner lumen with saline to increase the volume of the prosthesis at the time of use. The valve system may also be designed to facilitate postoperative saline volume adjustment by following the instructions provided in product literature.

3.1.6 *low bleed, n*—silicone gel implantable breast prostheses designed to have minimal silicone bleed when tested using the test method in 9.2.1.

3.1.7 *lumen, n*—a cavity within a shell of an implantable breast prosthesis.

3.1.7.1 *Discussion*—A lumen may contain either a fixed, non-adjustable volume of silicone gel, or it may be entirely or partly empty and intended to be inflated (filled) with saline. Inflatable lumens are accessible by valve to facilitate the addition of saline to adjust the volume of the prosthesis at the time of use. More than one lumen may be formed within a shell by silicone elastomer membrane partitions.

3.1.8 *orientation means, n*—any mark or palpable portion of an implantable breast prosthesis to assist the surgeon in positioning the implant.

3.1.9 *saline, n*—sodium chloride injection USP.

3.1.10 *shell, n*—a silicone elastomer continuous layer or membrane container (sac) that encloses a lumen or multiple lumens of an implantable breast prosthesis.

3.1.11 *silicone elastomer, n*—an elastomer containing crosslinked silicone polymer and fumed amorphous (non-crystalline) silica as a reinforcing filler.

3.1.12 *silicone gel, n*—a semisolid material consisting of a crosslinked silicone polymer network in which liquid silicone polymer is held (see definition of *gel* in Terminology F1251).

3.1.13 *valve, n*—user-sealable or self-sealing opening in an inflatable or gel saline prosthesis, extending from the exterior surface of the shell into a lumen, designed to facilitate adding or removing saline to or from the prosthesis to increase or decrease prosthesis volume.

4. Significance and Use

4.1 This specification contains requirements based on state-of-the-art science and technology as applicable to various considerations that have been identified as important to ensure reasonable safety and efficacy in implantable breast prostheses.

4.1.1 This specification is not intended to limit the science and technology which may be considered and applied to ensure performance characteristics of breast prostheses in intended applications. When new information becomes available or changes in state-of-the-art science and technology occur and relevance to prostheses has been established by valid science, it is intended that this specification will be revised in keeping with the new information or advances in state-of-the-art science.

5. Materials and Manufacture

5.1 *Silicone Elastomer*—Select and specify elastomers for use in implantable breast prostheses in keeping with Guides F2038 and F2042.

5.1.1 *Fabrication*—Fabrication techniques must necessarily be varied depending on the type of elastomer, the portion of an implantable breast prosthesis fabricated, its shape and its location, and function on the prosthesis.

5.1.2 *Vulcanization and Postcure*—Time and temperature of vulcanization and postcure must be adjusted with consideration of the elastomer type and the multi-step fabrication requirements of specific prostheses. Final postcure is typically done only after the shell or shells and all other portions have been completely assembled. Time and temperature of final postcure shall be adequate to drive the chemistry of vulcanization of all elastomers to completion and remove by-products of the cure in keeping with the chemical stoichiometry of the specific cure systems (for example, after postcure no additional vulcanization should occur when heated additionally at the recommended cure temperature).

5.2 *Silicone Gel*—Select and specify ingredients in keeping with Guides F2038 and F2042.

5.2.1 *Fabrication, Vulcanization, and Postcure:*

5.2.1.1 *Fabrication and Curing*—Unvulcanized liquid gel is typically placed in the lumen of a shell and cured and postcured *in situ* while the shell is maintained in its desired final shape. Fabrication techniques must necessarily be varied to satisfy the requirements of the specific implant type and shape.

5.2.1.2 *Vulcanization and Postcure*—The time and temperature of vulcanization and postcure shall be adequate to drive the vulcanization chemistry of the gel to completion in keeping with the chemical stoichiometry of specific silicone gels. When postcure is adequate, silicone gel does not undergo further vulcanization with additional heating at the cure temperature.

6. Volume and Dimensions

6.1 *Volumes of Prostheses:*

6.1.1 *Silicone Gel and Gel-Saline Prostheses*—Because silicone gel has a specific gravity of approximately one, volumes of silicone gel-containing prostheses are typically controlled by