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Standard Specification for Implantable Saline-Filled Breast Prostheses[1]

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1. Scope

1.1 This specification covers the requirements for single-use, saline inflatable, smooth and textured silicone shell implantable breast prostheses intended for use in surgical reconstruction, augmentation, or replacement of the breast.

1.2 *Limitations:*

1.2.1 This specification does not cover custom fabricated implantable breast prostheses.

1.2.2 This specification does not cover gel/saline type implants, which are within the scope of Specification F703.

1.3 *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.*

1.4 *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]

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D1349 Practice for Rubber—Standard Conditions for Testing

D3389 Test Method for Coated Fabrics Abrasion Resistance (Rotary Platform Abrader)

F604 Specification for Silicone Elastomers Used in Medical Applications (Withdrawn 2001)[3]

F703 Specification for Implantable Breast Prostheses

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F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)[3]

2.2 *Other Documents:*

USP (United States Pharmacopeia)[4]

Federal Register Title 21, Part 820[5]

Association for the Advancement of Medical Instrumentation[6]

ANSI/AAMI/ISO 10993-1 Biological Testing of Medical and Dental Materials and Devices—Part 1: Guidance on Selection of Tests[7]

ANSI/AAMI/ST50-1995 Dry Heat (Heated Air) Sterilizers[7]

ANSI/AAMI/ISO 11135-1994 Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization[7]

ANSI/AAMI/ISO 11137-1994 Sterilization of Health Care Products—Requirements for Validation and Routine and Routine Control—Radiation Sterilization[7]

ANSI/AAMI/ISO 11134-1993 Sterilization of Health Care Products—Requirements for Validation and Routine Control—Industrial Moist Heat Sterilization[7]

Parenteral Drug Association 1981 Technical Report No. 3, Validation of Dry Heat Processes Used for Sterilization and Depyrogenation[8]

FDA Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses[9]

3. Terminology

3.1 *Definitions:*

[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 F04.32 on Plastic and Reconstructive Surgery.

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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] United States Pharmacopeia, Vol XXI, Mack Publishing Company, Easton, PA 1989. Available from Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, NC 00852.

[5] Federal Register, Vol 43, No. 141, Friday, July 21, 1978 Part II. Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

[6] Available from Association for the Advancement of Medical Instrumentation (AAMI), 1110 N. Glebe Rd., Suite 220, Arlington, VA 22201-4795. http://www.aami.org.

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

[8] Available from Parenteral Drug Association (PDA), Bethesda Towers, 4350 East West Hwy., Suite 200, Bethesda, MD 20814. http://www.pda.org.

[9] Available from Food and Drug Administration (FDA), 5600 Fishers Ln., Rockville, MD 20857, http://www.fda.gov.

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

3.1.2 *inflatable breast prosthesis*—implantable breast prosthesis not containing silicone gel; implantable breast prosthesis designed and provided prefilled with saline or empty and to be filled with saline at the time of use to adjust the volume of the prosthesis.

3.1.2.1 *type 1, fixed volume inflatable breast prosthesis*—an implantable breast prosthesis composed of a single lumen, empty when supplied and having a valve to facilitate filling the lumen with saline at the time of use.

3.1.2.2 *type 2, variable volume inflatable breast prosthesis*—an implantable breast prosthesis composed of a single lumen, empty when supplied and having a valve to facilitate filling the lumen with a portion of the volume of saline at the time of use. The valve system is designed to facilitate further post-operative adjustment with saline as instructed in product literature.

3.1.2.3 *type 3, fixed volume inflatable breast prosthesis*—an implantable breast prosthesis composed of a single lumen, prefilled with saline by the manufacturer prior to time of use.

3.1.3 *lumen*—a cavity within a shell of an implantable breast prosthesis. Inflatable lumens are accessible by valve to facilitate the addition of saline to adjust the volume of the prosthesis at the time of use.

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

3.1.5 *saline*—only sodium chloride for injection (USP) is recommended for filling lumens of inflatable breast prosthesis.

3.1.6 *shell*—a silicone elastomer continuous layer or membrane container (sac) which encloses a lumen of an implantable breast prosthesis.

3.1.7 *silicone elastomer*—an elastomer containing cross-linked silicone polymer and fumed amorphous (non-crystalline) silica as a reinforcing filler.

3.1.8 *valve*—sealable or self-sealing opening in an inflatable prosthesis, extending from the exterior surface of the shell into a lumen, designed to facilitate addition of saline at the time of use or postoperatively to adjust prosthesis volume.

3.1.9 *patch*—a piece of silicone elastomer which covers and seals the hole which results from the manufacturing process of shell fabrication.

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 as it relates to the biocompatibility and the mechanical integrity of the device components in implantable breast prostheses.

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

5. Materials

5.1 *Silicone Elastomer*—Select and specify elastomers for use in implantable breast prostheses in keeping with Specification F604.

5.1.1 *Shell*—The following describes suitable silicone elastomer compositions for use as the primary material of construction of the shell including the exterior (tissue contact) surface:

polymer types	MQ or VMQ
fillers	A, B, or C
additive	J (for radiopacity)
catalysts	B, G, J, or K

NOTE 1—The compositions listed in this section are not intended to limit the compositions that may be used providing all other requirements of this specification are satisfied.

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

5.1.3 *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 elastomer to completion and remove by-products of the cure in keeping with the chemical stoichiometry of the specific cure system (e.g., after postcure no additional vulcanization should occur when heated additionally at recommended cure temperature).

5.1.4 *Physical Property Testing and Requirements*—Silicone elastomer shells shall demonstrate an acceptable response in physical property tests. Prostheses for testing should be selected from standard production batches which have gone through all manufacturing processes, including sterilization.

5.1.4.1 *Specimen Preparation*—Cut required tests specimens from shells with Test Method D412 dies. Devices or specimens shall be conditioned before testing for at least 1 h at 23 ± 2 °C (73.4 ± 3.6 °F).

5.1.4.2 *Dimension*—The individual shape, range of volume (displacement), base size, and anterior projection are determined by the manufacturer.

6. Volume and Dimensions

6.1 *Volumes of Prostheses:*

6.1.1 *Saline Inflatable Prostheses*—The designed or minimum and maximum recommended volume of saline fill shall be listed in instructions for use.

6.2 *Dimensions*—The ranges of shapes, volumes, base sizes, and anterior projections are determined by the manufacturer. Pertinent information shall be contained in the package insert.

7. Fixation Sites

7.1 The presence of fixation sites on any type of implantable breast prosthesis is optional. When used, the size and locations of fixation sites shall be clearly stated in instructions for use.

8. Orientation Means

8.1 Orientation means are optional features of subject prostheses. When orientation means are claimed, the location and recommended techniques for use shall be clearly described in instructions for use.

9. Test Methods and Requirements

9.1 *Biocompatibility:*

9.1.1 *Practice F748*—New or existing materials shall be in compliance with Practice F748 or other accepted standards such as ISO/AAMI/ANSI 10993-1. Assays recommended by Practice F748 include cell culture cytotoxicity assays; short-term intramuscular implantation assay; short-term subcutaneous assay; carcinogenicity; long-term implant test; systemic injection (acute toxicity) assay; sensitization assay; mutagenicity; and pyrogenicity.

9.1.2 *Silicone Saline-Filled Prostheses*—Test specimens for chronic implantation assays (carcinogenicity and long-term implant tests) shall be fabricated from the same combination of silicone elastomer and by the same or similar procedures and conditions used in fabricating prostheses. The thickness of shell in specimens shall be typical of thickness used in prostheses.

9.1.3 *Prior Biocompatibility Assays*—When prior biocompatibility data are available for silicone elastomer in clinical use in breast implants, even if not done by the exact protocols described in more standards, such data may satisfy all or part of the specific biocompatibility requirements of Practice F748 or equivalent methodology.

9.2 *Physical Properties:*

9.2.1 Unless otherwise specified, the standard temperature for testing shall be 23 ± 2 °C (73.4 ± 3.6 °F). When testing at any other temperature is required, use one of temperatures specified in Practice D1349. Tests are as follows:

9.2.2 *Shell Leakage Testing*—Fill a 5 to 8 qt stainless steel bowl with 70 % isopropyl alcohol. Submerge patched shell in bowl and gently apply pressure to the shell assembly. Visually inspect for any bubbles. Reposition shell in hand until entire surface of shell has been tested while exposed. Reject shells whenever any bubbles are seen.

9.2.3 *Shell*—Cut the test specimens from units made by standard production processes, including sterilization. Clean with appropriate (polar, for example, 2-propanol, or nonpolar, for example, 1,1,1-trichloroethane) solvent if necessary.

9.2.3.1 *Percent Elongation*—Three thickness measurements shall be taken prior to test, percentage elongation shall be 350 % minimum when tested in accordance with Test Method D412, Die C.

9.2.3.2 *Breaking Strength*—Ultimate breaking force in tension shall be no less when 2.5 lb (11.12 N) when tested in accordance with Test Method D412, Die C.

9.2.3.3 *Tensile Set*—The tensile set shall be <10 %, determine in accordance with Test Method D412. Determine tensile at 300 % elongation, stress the specimen for 3 min, then allow 3 min for relaxation.

9.2.3.4 *Fused or Adhered Joined*—Requirements for adhered or fused silicone rubber materials shall be critical to their integrity.

(1) Critical Fused or Adhered Joints—Joints or seams that are critical to the integrity of the prosthesis envelope shall not fail when the shell adjacent to the joint is stressed to 200 % elongation for 10 s (see Fig. 1).

(2) Noncritical Fused or Adhered Joints—Fused joints or seams that are bonded to the prosthesis envelope but are not critical to the envelope integrity (fixation sites, orientation means, valve covers, and so forth) shall not fail when the shell adjacent to the joint is stressed to 100 % elongation for 10 s (see Fig. 1).

9.3 *Shell Rupture/Failure Testing*—No standard test for assessing shell rupture has yet been developed. When such test method has been developed it will be added to this specification.

9.4 *Valve Competence:*

9.4.1 *Test Method*—Prior to testing, manipulate valve to duplicate its use for filling and inflate prosthesis with saline as described in instructions for use. Test such manipulated valve at both high and low retrograde pressures. Use air or other suitable gas, distilled water, or isotonic saline as test media. Pressures in order to be tested are 30 cm and 3 cm H_2O pressure, respectively. Maintain each test pressure for 5 min. When air or other suitable gases are tested, immediately immerse valve opening in water to check for leakage (bubbles). With water or isotonic saline check for droplets at the valve opening.

9.4.2 *Test Requirements*—No observable or detectable leakage.

9.5 *Abrasion Testing*—The criteria for shell abrasion in this testing have not been established.

9.5.1 *Abrasion Testing*—Wet method—see A1.1.

9.5.2 *Abrasion Testing*—Dry method—see A1.2.

9.5.3 Particle sizes generated by these test methods may not be able to be correlated with particulates resulting from clinical use, and therefore, has questionable meaning.

10. Sterilization

10.1 Implantable breast prostheses may be supplied presterilized in accordance with current AMI and PDA procedures and good manufacturing practices (GMP) established by FDA.

10.2 If user sterilization or re-sterilization of prostheses are intended, validated instructions for cleaning and sterilization shall be supplied with package insert.

11. Packaging, Labeling, and Package Inserts

11.1 *Packaging*—Prostheses shall be packaged to protect against damage and maintain cleanliness and sterility during the customary conditions of processing, storage, handling, and distribution.

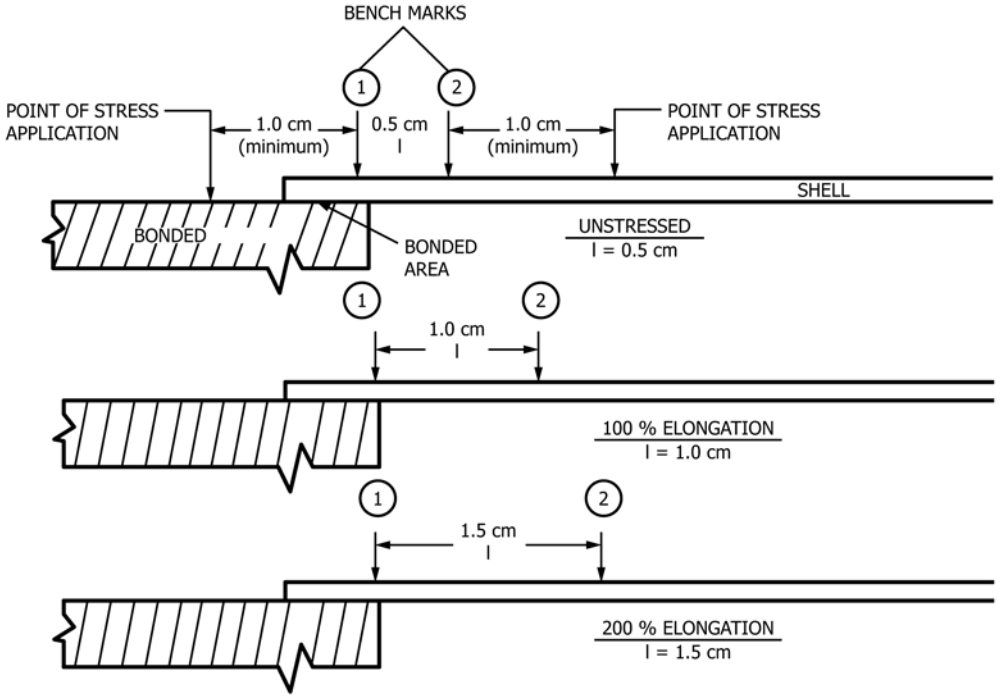

FIG. 1 Testing Fused or Adhered Joints

11.2 *Labeling*—Each package shall be labeled in a manner that ensures the labeling arrives at the point of use with the prostheses. The package labeling shall include the following information:

11.2.1 Manufacturer's name and address.

11.2.2 Product name, shape, type, and lot number.

11.2.3 Minimum and maximum volume and relevant dimension information.

11.2.4 Date (month and year) of sterilization or packaging and method of sterilization.

11.2.5 Special storage requirements, if any.

11.2.6 Self-adhering label suitable for application to the patient's medical records containing following information:

11.2.6.1 Prosthesis name and manufacturer.

11.2.6.2 Lot number.

11.2.6.3 Type and volume.

11.3 *Implant Marking*—Each implant unit shall be clearly and permanently marked with a manufacturer's unique identifying mark and the nominal volume of the device in millilitres (mL), or cubic centimetres (cc). The marking method shall not compromise the strength or integrity of the device.

11.4 *Package Insert*—Shall contain information: (*1*) to identify the manufacturer; (*2*) to describe the prosthesis; (*3*) on storage, handling, cleaning, sterilization, and re-sterilization; (*4*) to provide directions for use to the surgeon, and; (*5*) warnings and precautions concerning known and potential patient adverse reactions and risks.

12. Keywords

12.1 breast prosthesis; gel saline prosthesis; implant; saline inflatable prosthesis; silicone elastomer; soft tissue implant