Designation: F 2051 – 00

Standard Specification for Implantable Saline Filled Breast Prosthesis[1]

This standard is issued under the fixed designation F 2051; 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 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 F 703 (Standard Specification for Implantable Breast Prostheses).

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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 412 Test Methods For Rubber Properties in Tension[2]

D 1349 Recommended Practices for Rubber-Standard Temperatures and Atmospheres for Testing and Conditioning[2]

D 3389 Standard Test Method for Coated Fabrics Abrasion Resistance (Rotary Platform, Double-Head Abrader)[3]

F 604 Specification for Silicone Elastomers Used in Medical Applications[4]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[4]

F 1251 Standard Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices[4]

2.2 *Other Documents:*

USP (United States Pharmacopeia)[5]

Federal Register, Title 21, Part 820

Association for the Advance of Medical Instrumentation

ANSI/AAMI/ISO 10993-1, Biological Testing of Medical and Dental Materials and Devices – Part 1: Guidance on Selection of Tests

ANSI/AAMI/ST50-1995, Dry Heat (Heated Air) Sterilizers

ANSI/AAMI/ISO 111355-1994, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization

ANSI/AAMI/ISO 11137-1994, Sterilization of Health Care Products – Requirements for Validation and Routine and Routine Control – Radiation Sterilization

ANSI/AAMI/ISO 11134-1993, Sterilization of Health Care Products – Requirements for Validation and Routine Control – Industrial Moist Heat Sterilization

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

3. Terminology

3.1 *Definitions:*

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 prostheses not containing silicone gel – implantable breast prostheses 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

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[2] *Annual Book of ASTM Standards*, Vol 09.01.

[3] *Annual Book of ASTM Standards*, Vol 09.02.

[4] *Annual Book of ASTM Standards*, Vol 13.01.

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

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-art science and technology as applicable to various considerations that have been identified as important to assure 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 standard specification is not intended to limit the science and technology that may be considered and applied to assure performance characteristics of subject breast prostheses in intended applications. When new information becomes available or changes in state-of-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 F 604.

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 composition 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 D 412 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 *Standard Practice F 748*—New or existing materials shall be in compliance with Standard Practice F 748 or other accepted standards such as ISO/AAMI/ANSI 10993-1. Assays recommended by Standard Practice F 748 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 (carcnogenciity 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 F 748 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 Recommended Practice D 1349. 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 non polar, 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 D 412, Die C.

9.2.3.2 *Breaking Strength*—Ultimate Breaking Force in Tension shall be no less when 2.5 pounds (11.12 Newtons) when tested in accordance with test method D 412, Die C.

9.2.3.3 *Tensile Set*—The tensile set shall be < 10%, determine in accordance with Test Method D 412. 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.

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

9.2.3.4.2 Non-Critical 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, etc.) shall not fail when the shell adjacent to the joint is stressed to 100 % elongation for 10s (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 standard.

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.

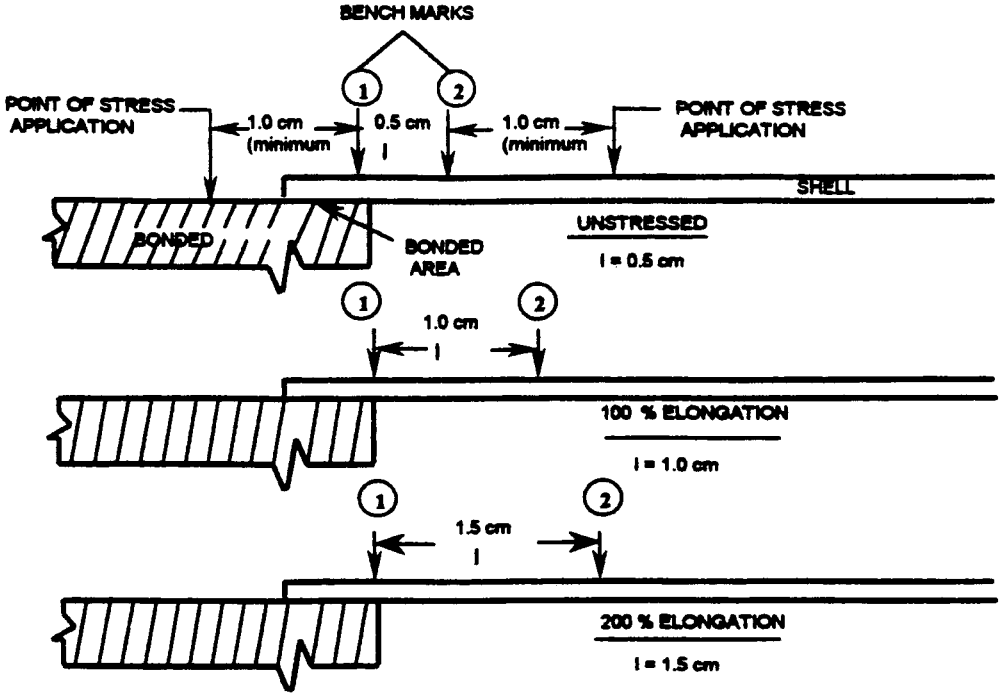

FIG. 1 Testing Fused or Adhered Joints

10. Sterilization

10.1 Implantable breast prostheses may be supplied pre-sterilized in accordance with current AMI and PDA procedures and good manufacturing practices (GMP) established by FDA.[6]

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, Labelling, 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.

11.2 *Labeling*—Each package shall be labelled in a manner that ensures the labelling arrives at the point of use with the prostheses. The package labelling 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 milliliters (ml), or cubic centimeters (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

[6] Federal Register, Vol. 43, No. 141, Friday, July 21, 1978 Part II.

ANNEX

A1. TEST METHODS FOR ABRASION TESTING

A1.1 Abrasion Test – Wet Method

A1.1.1 *Criteria*—The criteria for shell abrasion in this testing have not been established.

A1.1.2 *Test Limitations*—The conditions of this test method do not replicate physiological conditions. This test method is designed to accelerate the abrasion process in order to evaluate various implant designs/materials comparatively, in a reasonable time frame.

Validation of the repeatability and accuracy of this test method have not been demonstrated. Typically a Round Robin test battery at different laboratories at different locations around the country is done for this validation.

A1.1.3 *Testing and Requirements*:

Test equipment and fixtures:

- Teledyne Taber® Abraser Model 5130 or 5150.
- Aluminum wheels 2.062″ O.D. × 0.625″ I.D. × 0.500″ W.
- 140-57 Auxiliary Weights (1000 gram load).
- Taber S-31 glass mounting plates.
- 6″ Aluminum specimen holder.
- 1.417″ Dia cylinder mandrel for silicone wheel cover fabrication (approx. 6″ length).
- RTV adhesive.

A1.1.3.1 *Test Sample*— Adhere approx. 5″ Dia silicone test specimen on glass mounting plate. Weigh the specimen plus glass mounting plate on analytical balance to determine its initial equilibrated mass. Cover aluminum wheel with silicone band made by dipping from cylinder mandrel, fill air gaps between silicone cover and aluminum wheel with RTV adhesive.

A1.1.3.2 Place glass mounting plate with test specimen on specimen holder. Secure test sample to holder by tightening the finger nut. Place silicone covered wheel onto abrading arm. Tighten in place. Place 1,000 gram weight onto arm. Lower arm until the silicone covered wheels contact with test surface.

A1.1.3.3 *Testing*—Add 40-50 ml's of physiological saline to specimen holder. Press ON key to energize the Taber abrader. Set the number cycles for the abrasion testing to 10,000. Press start key to initiate testing. Testing will cease after 10,000 cycles have been completed. Ensure saline is covering test area during the testing.

A1.1.3.4 After 10,000 cycles, remove specimen from the tester and gently wipe away any loose abraded material from the surface of the sample. Saline may be used to flush any loose abraded particles. Be careful to avoid contacting the abraded area of the test specimen while cleaning. Using microscope, examine specimen for failure. Look for worn areas or tears on surface of test specimen. Repeat testing and examining specimens every 10,000 cycles or until specimen fails.

A1.1.3.5 If failure has occurred, carefully remove the specimen and record number of cycles. Place sample on metal tray in an oven for 1 hour at 115°C (239°F ± 9°F). Using tweezers, remove specimen from the oven and let cool to room temperature at least 1 hour. Record specimen weight, and cumulative weight change.

A1.1.4 *Calculation*:

A1.1.4.1 Calculate the loss in mass as follows:

Mass loss per revolution, g = original mass (before test) – final mass (after test)/number of revolutions.

A1.2 Abrasion Test – Dry Method

A1.2.1 *Criteria*—The criteria for shell abrasion in this testing have not been established.

A1.2.2 *Test Limitation*— The conditions of this test method do not replicate physiological conditions. This test method is designed to accelerate the abrasion process in order to evaluate various implant designs/materials comparatively, in a reasonable time frame.

Validation of the repeatability and accuracy of this test method have not been demonstrated. Typically a Round Robin test battery at different laboratories at different locations around the country is done for this validation.

A1.2.3 *Testing and Requirements*:

Test Equipment and Fixtures:

- Taber 5-12 Long Handle Brush
- Aluminum Wheels 2.026″ OD × 0.625 ID × 0.50 W
- RTV adhesive
- Taber S-16 Steel Mounting Plates
- Teledyne Taber Abraser Model 5130 or 5150
- Hexane, greater than 95 %
- 140-57 Auxiliary Weights (1,000 gram load)
- Analytical Balance, Accurate to 0.1 mg or equivalent
- 1.417″ DIA cylinder mandrel for silicone wheel cover fabrication (approx. 6″ length)
- Temperature Humidity Chamber (to contain Taber Abraser)

A1.2.3.1 *Test Sample*— S-16 Specimen plates and aluminum wheels are soaked in Hexane for the removal of oil and contaminants and dried.

NOTE A1.1—**Caution:** Exercise Caution while using Hexane. Using RTV adhesive adhere approximately 5″ diameter silicone test specimen on S-16 mounting plate removing all air bubbles before curing. Weigh the specimen plus mounting plate on an analytical balance to determine its initial equilibrated mass. Cover aluminum wheels with silicone band made by dipping from cylinder mandrel; fill air gaps between silicone cover and aluminum wheel with RTV adhesive.

A1.2.3.2 Place specimen plate with test specimen on specimen holder. Secure test sample to holder by tightening the finger nut. Place silicone covered wheels on to abrading arms and tighten in place. Place 1,000 gram weight on to each arm. Lower arms until the silicone wheels contact with test surface.

A1.2.3.3 *Testing*—Press ON key to energize the Taber abrader. Set the number of cycles for the abrasion testing to 6,000. Press start key to initiate testing. Testing will cease after 6,000 cycles have been completed.

A1.2.3.4 After completion of 6,000 cycles, the specimen plate shall be removed and gently brushed with the Taber-512 long handled brush to remove particles. The specimen weight shall be recorded. Repeat testing and examining specimen every 6,000 cycles for a total of 30,000 cycles.

A1.2.3.5 For relative comparisons, samples having higher weight loss after 30,000 cycles are considered “less abrasion resistant”.

A1.2.4 *Calculation*:

A1.2.4.1 Calculate the loss in mass as follows:

Total mass loss; g = original mass (before test)-final mass (after test).

Mass loss per revolution; g = original mass (before test) – final mass (after test)/number of revolutions.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Implantable saline filled breast prostheses are soft tissue implants used to simulate breast tissue in surgical procedures for breast augmentation, reconstruction, or replacement.

X1.2 Implantable breast prostheses are constructed with continuous, closed outer shells of silicone elastomer in various shapes, sizes, and combinations. Lumen is the space enclosed by the shell. The lumen of saline inflatable prostheses may be prefilled or empty as supplied and filled through a valve at the time of use with isotonic, injection grade saline in fixed or variable volume.

X1.2.1 Saline filled breast implants are known to fail from abrasion occurring in shell folds. To minimize the occurrence of shell folds these implants should be filled to the proper volume. Proper fill volume is determined at surgery and must not be less than the nominal implant volume or exceed the manufacturers recommended maximum.

X1.3 The only material currently acceptable as material of construction for implantable saline filled breast prostheses is silicone elastomer. This specification addresses the composition and vulcanization/cure of silicone elastomer and the physical properties of materials as determined from specimens obtained from final prostheses. These requirements include bonded (fused, adhered or joined) areas of the shells.

X1.3.1 There are a variety of other tests and considerations that have been proposed for incorporation into this specification including total energy to rupture, cyclic compression testing, specific chemical characterization of all silicone species, and others as such contained in FDA’s *Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses*. These proposals merit consideration, and the current content of this standard is not intended to limit its revision and updating to appropriately reflect changes and advancements in the state-of-the-art and the availability of relevant consensus test methods. The current content of this

standard is believed to accurately represent currently available technology where there has been consensus on test methods and requirements.

X1.4 To ensure integrity of subject prostheses, this specification contains provisions for testing shells and any associated inflation valves for leakage.