Designation: F 703 – 96 (Reapproved 2002)ε1

Standard Specification for Implantable Breast Prostheses[1]

This standard is issued under the fixed designation F 703; 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—A reference to Appendix 2 was editorially corrected in paragraph 9.1 in June 2006.

1. Scope

1.1 This specification covers the requirements for silicone gel-filled, saline inflatable silicone gel-filled, and saline inflatable, smooth-shell 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 The values stated in SI units are to be regarded as the standard. The inch-pound units given in parentheses are for information only.

1.4 *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:* [2]

D 412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D 1349 Practice for Rubber—Standard Temperatures for Testing

F 604 Specification for Silicone Elastomers Used in Medical Applications[3]

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

F 1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices

3. Terminology

3.1 *Definitions:*

3.1.1 *barrier coat*—a silicone elastomer layer as a part of the shell of a silicone gel implantable breast prostheses that retards silicone bleed.

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

3.1.3 *fused or adhered joints (seams)*—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*—diffusion of liquid silicone components of silicone gel through the shell of an implantable breast prosthesis.

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

3.1.5.1 *Type I*—a fixed volume gel filled breast prosthesis—implantable breast prosthesis comprised of a single lumen containing a fixed amount of silicone gel. The lumen of Type I breast prostheses is not accessible for volume adjustments of any kind.

3.1.5.2 *Type II*—double lumen inflatable gel filled breast prosthesis—an implantable breast prosthesis comprised of two complete lumens, one inside the other. The inner lumen 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, only at the time of use.

3.1.5.3 *Type III*—reverse double lumen inflatable gel filled breast prosthesis—an implantable breast prosthesis comprised of two complete lumens, one inside the other. The volume 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 is also designed to facilitate post-operative volume adjustment by following the instructions provided in product literature.

[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.

Current edition approved June 10, 1996. Published May 1997. Originally published as F 703 – 81. Last previous edition F 703 – 81 (1986).

[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] Withdrawn.

3.1.6 *inflatable breast prosthesis*—implantable breast prostheses not containing silicone gel—implantable breast prostheses designed and provided empty and to be filled, all or in part, with saline at the time of use to adjust the volume of the prosthesis.

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

3.1.6.2 *Type II—adjustable inflatable breast prosthesis*, an implantable breast prosthesis comprised of a single lumen, empty when supplied and having a valve to facilitate filling the lumen with a system is designed to facilitate further postoperative adjustment with saline as instructed in product literature.

3.1.7 *low bleed*—silicone gel implantable breast prostheses designed to have minimal silicone bleed when tested by the method in 9.1.1.

3.1.8 *lumen*—a cavity within a shell of an implantable breast prosthesis. A lumen may contain either a fixed, nonadjustable 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.

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

3.1.10 *saline*—only sodium chloride injection USP is recommended for filling lumens of implantable breast prosthesis.

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

3.1.12 *silicone elastomer*—an elastomer containing crosslinked silicone polymer and fumed amorphous (noncrystalline) silica as a reinforcing filler.

3.1.13 *silicone gel*—a semisolid material consisting of a crosslinked silicone polymer network in which liquid silicone polymer is held (see definition of *gel* in Terminology F 1251).

3.1.14 *valve*—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 addition of saline at the time of use to fill the prosthesis and increase prosthesis volume.

4. Materials and Manufacture

4.1 *Silicone elastomer*—Select and specify elastomers for use in implantable breast prostheses in keeping with Specification F 604.

4.1.1 *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

4.1.2 *Barrier Coatings*—The following are suitable compositions of for use in barrier coat elastomers:

Polymer composition	FVMQ or VMP_2 M_2 Q
Fillers	B or C
Catalyst/cure	J or K

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

4.1.3 *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.

4.1.4 *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 recommended cure temperature).

4.1.5 *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. With silicone gel prostheses, remove gel and clean shell with appropriate polar (for example, 2-propanol) or non-polar (aliphatic, aromatic, or chlorinated hydrocarbon) solvent, or both. If solvent cleaned, condition shell afterwards for 3 h 150°F (65.6°C) in an air circulation oven to remove solvent.

4.1.5.1 *Specimen Preparation*—Cut required tensile test specimens from shells with Test Methods D 412 dies. Specimens shall be conditioned before testing for at least 3 h at 23 ± 2°C (73.4 ± 3.6°F).

4.1.6 *Test Procedure*— 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 the temperatures specified in Practice D 1349. Requirements are as follows:

4.1.6.1 *Percent Elongation*—Percent elongation shall be 350 % minimum when tested in accordance with Test Methods D 412.

4.1.6.2 *Breaking Strength*—Ultimate breaking force in tension shall be no less than 11.12 N (2.5 lbs) when tested in accordance with Test Methods D 412.

4.1.6.3 *Tensile Set*— Determine tensile set at 300 % elongation, stress the specimen for 3 min then allow 3 min for relaxation. The tensile set shall be <10 %, determined in accordance with Test Methods D 412.

4.1.6.4 *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).

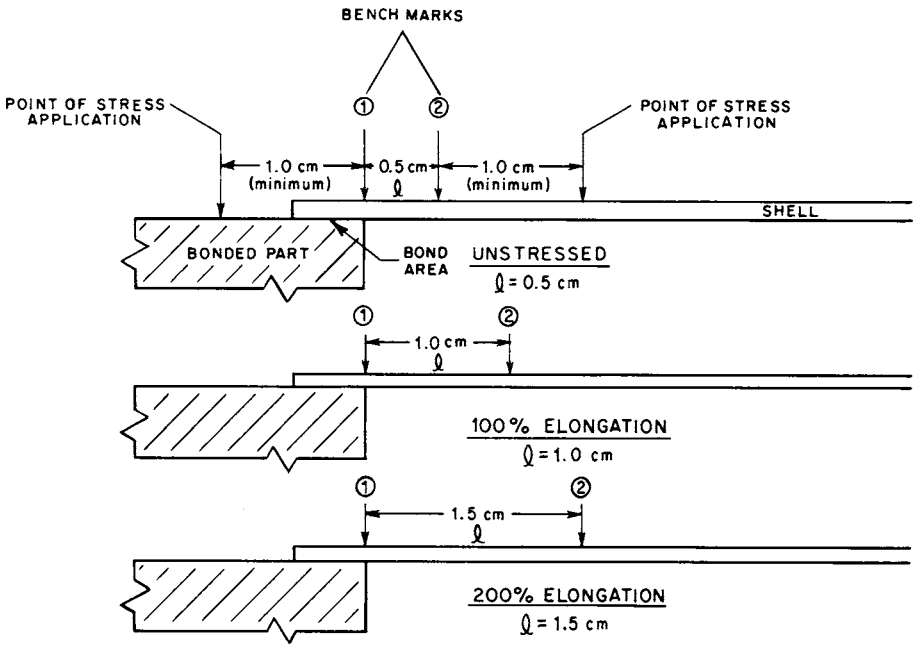

FIG. 1 Testing Fused or Adhered Joints

4.1.6.5 *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 10 s (see Fig. 1).

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

4.1.8 *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.

4.2 *Silicone Gel*—Select and specify ingredients in keeping with Specification F 604.

4.2.1 *Polymers and Catalysts*—The following are suitable for use in silicone gel:

Polymers	MQ and VMQ blend
Filler	A (no filler or additive)
Catalyst/cure	J or K

4.2.2 *Fabrication, Vulcanization and Postcure*:

4.2.2.1 *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.

4.2.2.2 *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 cure temperature.

4.2.3 *Testing and Requirements*:

4.2.3.1 *Specimens*—Remove test samples of gel from finished production batches of silicone gel—containing implantable breast prostheses after all manufacturing, including sterilization has been completed.

4.2.3.2 *Weight Loss From Heating*—When a 2 to 3 g sample is spread in an aluminum weighing cup and heated in an air circulating oven for 4 h at approximately 150°C the weight loss shall not exceed 1 %.

4.2.4 *Gel Cohesion*:

4.2.4.1 *Cone/Pendant Gel Test Method Described in Appendix X1*—This test is particularly useful to manufacturers for use in silicone gel development and quality control and quality control of unused silicone gel breast implants in that it provides quantitative results. The cohesive properties of silicone gel shall be considered suitable for use in silicone gel breast prostheses in the length of the pendant gel remains <4.5 cm when tested in accordance of the method in Appendix X1.

NOTE 2—The test results from cone/pendant gel testing are highly dependent on strict adherence to the specifications for the test apparatus and the procedures described in Appendix X1. A similar method contained in the 1986 edition and earlier editions of this specification was reported by most who used it to give highly variable and erratic results resulting in modifications of the test method as contained in Appendix X1. Precision and bias data for this method has not been established.

4.2.4.2 *Hypodermic Syringe/Pendant Gel Test Method*—A pass/fail test methods that can be used as an alternative to the cone/pendant gel test of 4.2.4.1. This test method may be applied by surgeon users, manufacturers, and others for evaluating the cohesive properties of silicone gel in breast prostheses including the gel from used, explanted devices.

4.2.5 *Test Fixture*— 60 cm^3 plastic hypodermic syringe with barrel having inside diameter of 26 to 28 mm. Prepare for use by sharply cutting off the tapered end circumferentially flush with the 0 cm^3 line leaving an unobstructed open barrel.

4.2.6 *Test Sample*—Cut the shell of the prosthesis to be tested diametrally across the apex from edge to edge. Push the plunger of the syringe forward until it is flush with the cut end of the barrel. Insert the plunger end of the syringe well into the gel on one side of the prosthesis and slowly draw the gel into syringe until the plunger is flush with the 60 cm^3 line. Care must be exercised to avoid drawing in either air or the shell. After one minute cut the gel sharply across the cut end of the syringe with scissors and remove syringe with test sample. Discard any samples where air was drawn in or if the shell interrupted obtaining the sample. With care, two gel samples may be obtained from most prosthesis.

4.2.7 *Testing*—Suspend the syringe in a vertical position with the open end down and at least 25 cm above a flat surface. Slowly move the plunger from the 60 cm^3 line to the 40 cm^3 line to extrude an unsupported 20 cm^3 gel mass and commence timing.

4.2.8 *Requirements*—The gel is considered to have passed this test if, after 30 min, all of the gel remains attached as a mass at the end of the open syringe barrel no liquid drops are visible. The test should be repeated if the whole mass falls from the syringe.

NOTE 3—The precision and bias of the syringe/pendant gel test method has not been established.

NOTE 4—Correlation between the cone/pendant gel and syringe tests has not been established.

5. Volume and Dimensions

5.1 *Volumes of Prostheses*:

5.1.1 *Silicone Gel and Gel-Saline Prostheses*—Volumes of silicone gel-containing prostheses are typically controlled by weight, 1 g = approximately 1 cm^3. Weight tolerances of silicone gel-containing prostheses with volume ≥250 cm^3 shall be ±5 g, and when prostheses volume <250 cm^3 weight tolerance shall be ±2 % of labeled volume in equivalent grams.

5.1.2 *Saline Inflatable and Gel-Saline Prostheses*—The design or maximum recommended volume of saline fill shall be listed in instructions for use.

5.2 *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.

6. Significance and Use

6.1 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.

6.1.1 This specification is not intended to limit the science and technology which 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 keeping with this new information or advances in state-of-the-art science.

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. Gel Bleed

9.1 *Test Method*—See Appendix X2.

9.1.1 *Requirements*—The allowable quantities of gel bleed in this testing have not been established.

10. Biocompatibility

10.1 *Practice F 748*—Biocompatibility assays of materials with no or limited history of prior biocompatibility testing and successful clinical use for implant applications shall follow guidelines of Practice F 748. Assays recommended by 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.

10.1.1 *Silicone Gel Prostheses*—Test specimens for chronic implantation assays (carcinogenicity and long term implant tests) shall be fabricated from the same combination of silicone elastomer and gel 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.

NOTE 5—To minimize palpability of prostheses and to effectively mimic the softness of breast tissue, silicone gels used in implantable breast prostheses must be soft (have low modulus). State-of-the-art silicone gels with required low modulus are also low strength. When implanted long term without an enclosing silicone elastomer shell, silicone gel may not retain its physical shape and integrity. Clinical implantation of free silicone gel sans shell is neither intended nor recommended. If shell rupture occurs in an implanted silicone gel breast prostheses resulting in direct contact between silicone gel and tissue, revision surgery for removal of ruptured prostheses and any free gel is recommended, with or without prosthetic replacement. To help assure relevancy of long term biocompatibility assays in animals to recommended clinical use of silicone gel implantable breast prostheses, the specimens used in chronic biocompatibility assays shall have silicone gel contained in an enclosing silicone elastomer shell, similar to silicone gel prostheses. Specimens of free silicone gel may be used in all other biocompatibility assays as specified in Practice F 748 for implants used in tissue and tissue fluid contact applications, including short term intramuscular implantation assay.

10.1.2 *Prior Biocompatibility Assays*—When prior biocompatibility data are available for silicone elastomers and gels that may also have histories of use in clinical use in breast implants, even if not done by the exact protocols described in more recently developed biocompatibility test method standards, such data may satisfy all or part of the specific biocompatibility requirements of Practice F 748.