



Standard Specification for Implantable Breast Prostheses¹

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

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F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)³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

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.

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:

Saline, Silicone Gel, and Alternative Breast Implants—Guidance for Industry and FDA Staff, November 17, 2006⁴

ISO/AAMI/ANSI 10993-1 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing⁵

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 silicone gel.

(1) *Discussion*—The lumen of a Type I breast prostheses 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.

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>.