



Standard Specification for Implantable Saline Filled Breast Prosthesis¹

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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 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

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F604 Specification for Silicone Elastomers Used in Medical Applications (Withdrawn 2001)³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F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)³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 820⁵

Association for the Advancement of Medical Instrumentation⁶

ANSI/AAMI/ISO 10993-1 Biological Testing of Medical and Dental Materials and Devices—Part 1: Guidance on Selection of Tests⁷

ANSI/AAMI/ST50-1995 Dry Heat (Heated Air) Sterilizers⁷

ANSI/AAMI/ISO 11135-1994 Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization⁷

ANSI/AAMI/ISO 11137-1994 Sterilization of Health Care Products—Requirements for Validation and Routine and Routine Control—Radiation Sterilization⁷

ANSI/AAMI/ISO 11134-1993 Sterilization of Health Care Products—Requirements for Validation and Routine Control—Industrial Moist Heat Sterilization⁷

Parenteral Drug Association, 1981 Technical Report No. 3, Validation of Dry Heat Processes Used for Sterilization and Depyrogenation⁸

FDA Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses⁹

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.

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>.