



Standard Specification for Soft-Tissue Expander Devices¹

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1. Scope

1.1 This specification covers the requirements for single use saline inflatable, smooth and textured tissue expansion devices to be used intraoperatively or implanted for typically less than 6 months and then removed.

1.2 Limitations:

1.2.1 This specification applies only to soft-tissue expander devices fabricated with elastomer shells. It does not necessarily cover any custom fabricated soft tissue expander device manufactured to any other specification.

1.2.2 This specification applies, in part, to combination “expander/mammary” devices as classified in Section 4.

1.3 The values stated in SI units are to be regarded as standard, values in parentheses are for information only.

1.4 The following statement pertains only to the test methods and requirements portion, Section 9, of this specification. *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

D624 Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers

D1349 Practice for Rubber—Standard Conditions for Testing

F703 Specification for Implantable Breast Prostheses

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

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.

F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)³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

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:

Federal Register, Title 21, Part 820⁴

USP (United States Pharmacopoeia)⁵

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 Tests⁶

ANSI/AAMI/ST50 Dry Heat (Heated Air) Sterilizers⁶

ANSI/AAMI/ISO 11135 Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization⁶

ANSI/AAMI/ISO 11137 Sterilization of Health Care Products—Requirements for Validation and Routine and Routine Control—Radiation Sterilization⁶

ANSI/AAMI/ISO 11134 Sterilization of Health Care Products—Requirements for Validation and Routine Control—Industrial Moist Heat Sterilization⁶

Parenteral Drug Association 1981 Technical Report No. 3, Validation of Dry Heat Processes Used for Sterilization and Depyrogenation⁷

3. Terminology

3.1 Definitions:

³ The last approved version of this historical standard is referenced on www.astm.org.

⁴ 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>.

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

⁶ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.

⁷ Available from the Parenteral Drug Association, 3 Bethesda Medical Center, Suite 1500, Bethesda, MD 20814.