Designation: F1441 – 03 (Reapproved 2014)

Standard Specification for Soft-Tissue Expander Devices[1]

This standard is issued under the fixed designation F1441; 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 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

F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)[3]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 820[4]

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 Tests[6]

ANSI/AAMI/ST50 Dry Heat (Heated Air) Sterilizers[6]

ANSI/AAMI/ISO 11135 Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization[6]

ANSI/AAMI/ISO 11137 Sterilization of Health Care Products—Requirements for Validation and Routine and Routine Control—Radiation Sterilization[6]

ANSI/AAMI/ISO 11134 Sterilization of Health Care Products—Requirements for Validation and Routine Control—Industrial Moist Heat Sterilization[6]

Parenteral Drug Association 1981 Technical Report No. 3, Validation of Dry Heat Processes Used for Sterilization and Depyrogenation[7]

3. Terminology

3.1 *Definitions:*

[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 Oct. 1, 2014. Published November 2014. Originally approved in 1992. Last previous edition approved in 2009 as F1441 – 03 (2009). DOI: 10.1520/F1441-03R14.

[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] 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 Pharmacopeia*, Vol XXI, Mack Publishing Company, Easton, PA 1989. Available from Pharmacopeia 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.

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3.1.1 *injection port*—the port through which an injection to inflate or deflate the variable volume device is made.

3.1.1.1 *remote port*—a port that is remote from the shell and attached to the shell by means of tubing.

3.1.1.2 *self-contained (integrated) port*—a port that is integral to the device shell.

3.1.2 *injection surface*—the area of the injection port recommended by the manufacturer for needle insertion to inflate or deflate the device.

3.1.3 *needle stop*—the injection port component used to limit hypodermic needle penetration through the port.

3.1.4 *silicone elastomer*—an elastomer containing cross-linked silicone polymer and fumed amorphous (non-crystalline) silica as a reinforcing filler.

3.1.5 *reinforced silicone elastomer*—a composite of silicone elastomer and an embedded textile made from polyethylene terephthalate (such as Dacron (trademark)) fibers.

3.1.6 *shell*—a silicone elastomer continuous layer or membrane container (sac) which encloses a lumen of a soft tissue expander.

3.1.7 *patch or base*—a piece of silicone elastomer or reinforced silicone elastomer, which covers and seals the hole which results from the manufacturing process of shell fabrication.

3.1.8 *lumen*—a cavity within a shell and patch or base, accessible by an injection port, to facilitate the addition of saline to adjust the volume of the soft tissue expander.

3.1.9 *tubing length adapter*—the tissue expander component used to connect more than one piece of remote port tubing.

3.1.10 *tubing/shell junction*—the junction of the remote port tubing to the shell of the tissue expander.

3.1.11 *fused or adhered joints (seams)*—sites in the shell or other parts of the tissue expander device where materials have been joined (fused or bonded) together, with or without adhesive, as part of the manufacturing process.

3.1.12 *orientation means*—any mark or palpable portion of a soft tissue expander to assist the surgeon in positioning.

3.1.13 *saline*—only sodium chloride for injection (USP) is recommended for filling lumens of soft tissue expanders.

3.2 For other terms used in this specification see Terminology F1251.

4. Classification

4.1 *Type I: Chronic Tissue Expansion Device*—A soft tissue expander device intended to be inflated postoperatively.

4.2 *Type II: Immediate Tissue Expansion Device*—A soft tissue expander device only intended for intraoperative use.

4.3 *Type III: Combination Expander/Mammary Device*—A specific type of soft tissue expander device intended to be implanted for postoperative expansion of the breast and further indicated for long term implantation as a breast prosthesis.

4.3.1 *Gel/Saline*—Expansion indications for devices of this type shall confirm to this specification in addition to Specification F703, as applicable.

4.3.2 *Saline Only*—Expansion indications for devices of this type shall confirm to this specification in addition to Specification F2051, as applicable.

5. Significance and Use

5.1 This specification contains requirements based on state-of-art science and technology as applicable to various considerations that have been identified as important to ensure reasonable safety and efficacy as it relates to the biocompatibility and the mechanical integrity of the device components in soft tissue expander devices.

5.1.1 This specification is not intended to limit the science and technology that may be considered and applied to ensure performance characteristics of subject device in intended applications. When new information becomes available or changes in state-of-art science and technology occur and relevance to subject devices has been established by valid science, it is intended that this specification will be revised in accordance with ASTM guidelines.

6. Volume and Dimensions

6.1 *Volumes of Devices*—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 soft tissue expander device 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 devices. 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 *Practice F748*—New or existing materials shall be in compliance with Practice F748 or other accepted standards such as ANSI/AAMI/ISO 10993-1. Assays recommended by Practice F748 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 *Soft Tissue Expander Devices*—Test specimens for chronic implantation assays (carcinogenicity 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 devices. The thickness of shell in specimens shall be typical of thickness used in devices.

9.1.3 *Prior Biocompatibility Assays*—When prior biocompatibility data are available for silicone elastomer in clinical use for tissue expansion, 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 Practice F748 or equivalent methodology.

9.2 *Physical Properties:*

9.2.1 Tissue expander or component designs, or both, shall demonstrate an acceptable response to the following tests. Devices for testing should be selected from standard production batches which have gone through all manufacturing processes, including sterilization. Unless otherwise specified, the standard temperature for testing shall be 23 ± 2°C (73.4 ± 3.6°F). Condition the test specimens for at least 3 h when the test temperature is not 23 ± 2°C. If the material is affected by moisture, maintain the relative humidity at 50 ± 5 % and condition the specimen for at least 24 h prior to testing. When testing at any other temperature is required, use one of the temperatures specified in Practice D1349.

9.2.2 *Shell*—Cut the test specimens from units made by standard production processes including sterilization. Clean with appropriate (polar, for example, 2-propanol, or nonpolar, for example, 1,1,1-trichloroethane) solvent if necessary.

9.2.2.1 *Tensile Set*—At 300 % elongation, stress the test specimens for 3 min. Remove the load, then allow 3 min for relaxation. Test the set in accordance with Test Methods D412 with the exception of sample thickness and cycle time. Maximum set shall be less than 10 %.

9.2.2.2 *Breaking Force*—Test ultimate breaking force in tension in accordance with Test Methods D412 Die C with the exception of sample thickness. Ultimate breaking force in tension shall be no less than 11.12 N (2.5 lb).

9.2.3 *Tubing Shell Junction*—The tubing/shell junction of Type I tissue expanders shall not fail when tested under the following conditions:

9.2.3.1 *Tubing Greater Than 2.3 mm (0.090 in.) in Outer Diameter*—The tubing/shell junction shall not fail when stressed to 6.672-N (1.5-lb) tension.

9.2.3.2 *Tubing Less Than or Equal to 2.3 mm (0.090 in.) in Outer Diameter*—The tubing/shell junction shall not fail when stressed to 2.224-N (0.5-lb) tension.

9.2.4 *Injection Port Competence*—There shall be no Type I tissue expander port leakage observed when an injection port is tested under the following conditions. Apply 120-mm Hg intraluminal pressure to the port using water or test media with demonstrated equivalence. Using the prescribed gauge hypodermic needle, puncture the port 5 consecutive times within 1 mm^2 at a site near the center of the port. The port is considered leaking and fails the test if beads of fluid on the port surface are not static after 30 s.

9.2.4.1 *21 Gage Port*—An injection port may be labelled a 21 G port only if it passes the injection port competence test when tested with a 21 G hypodermic needle.

9.2.4.2 *23 Gage Port*—An injection port may be labelled a 23 G port only if it passes the injection port competence test when tested with a 23 G hypodermic needle.

9.2.4.3 *25 Gage Port*—An injection port may be labelled a 25 G port only if it passes the injection port competence test when tested with a 25 G hypodermic needle.

9.2.5 *Overexpansion*—There shall be no leakage or device rupture when the tissue expander is expanded (using water at ambient conditions) to 200 % of its maximum recommended inflation volume and kept at that volume for a minimum of 10 min.

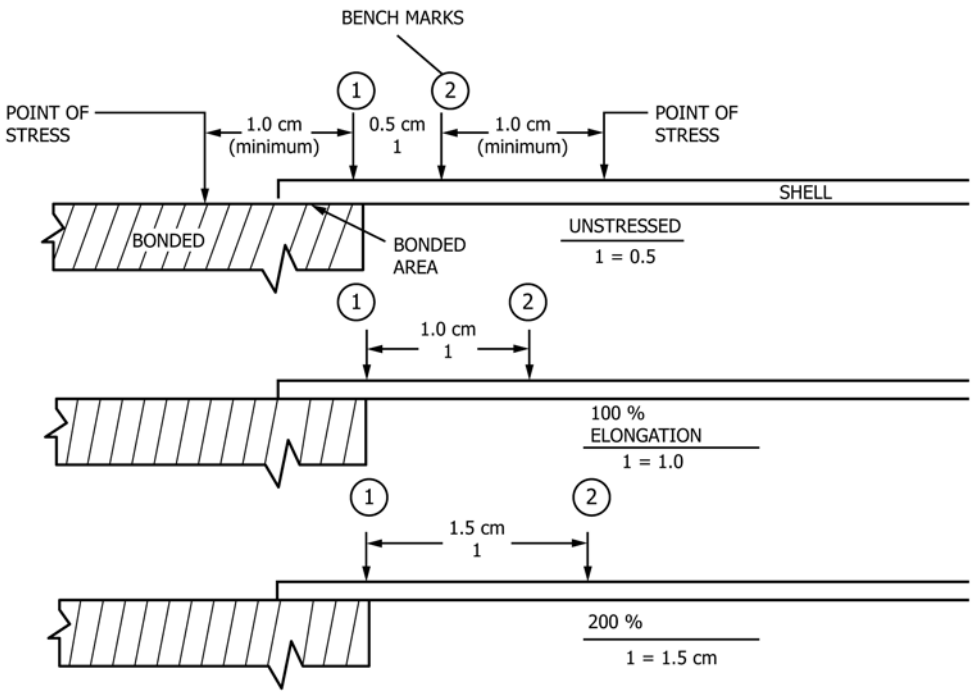

FIG. 1 Testing Fused or Adhered Joints

9.2.6 *Tubing Length Adapter Strength*—Two pieces of remote port tubing attached by means of the tubing length adapter shall not separate when a 152.4-mm (6-in.) test specimen is stressed at 10 % elongation. Tubing length adapter shall not be ligated in this test method.

9.2.7 *Needle Stop Penetration*—Mount a 38.1-mm (1.5-in.) 21-gage hypodermic needle to a syringe. Insert the needle into the injection port, perpendicular to the needle stop. Apply force along the axis of the needle, to push it into the needle stop. The needle must fail without penetrating the needle stop.

9.2.8 *Fused or Adhered Joints*—Requirements for adhered or fused materials shall be critical to their integrity.

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

9.2.8.2 *Non-Critical Fused or Adhered Joints*—Adhered or fused joints or seams that are bonded to the device envelope, but are not critical to the envelope integrity (fixations, suture tabs, orientation bars, and so forth) shall not fail when the shell adjacent to the joint is stressed to 100 % elongation for 10 s (see Fig. 1).

10. Sterilization

10.1 The units may be supplied pre-sterilized in accordance with current AMI and PDA procedures and good manufacturing practices (GMP) established by the FDA.[8]

10.2 If user sterilization of the device is intended, validated instruction for cleaning and sterilization shall be supplied with the package insert.

11. Packaging, Labelling, and Package Inserts

11.1 *Packaging*—The devices shall be packaged to protect them from damage, including maintenance of sterilization of pre-sterilized devices, during the customary conditions of processing, storage, handling, and distribution.

11.2 *Labelling:*

11.2.1 Each package shall be labelled in a manner that ensures the labelling arrives at the point of use with the device. The package labelling shall include the following information:

11.2.1.1 Product name,

11.2.1.2 Configuration or type,

11.2.1.3 Manufacturer's name and address,

11.2.1.4 Manufacturer lot number,

11.2.1.5 Volume or dimension,

11.2.1.6 Date of sterilization or packaging (year), and

11.2.1.7 Special storage requirements, if any.

11.2.2 With each unit, a self-adhering tab shall be provided which is suitable for attaching to the patient's chart. The tab shall include the following information:

11.2.2.1 Product name and manufacturer,

11.2.2.2 Product lot number, and

11.2.2.3 Product type and volume dimension.

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 millilitres (mL), or cubic centimetres (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 elastomer; expander; implant; implant material; medical device; plastic surgery; soft tissue expander

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

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Tissue expanders are intended for use as temporary devices that are surgically placed under the muscle or in subcutaneous soft tissue. To ensure biological safety of the materials and finished devices, this specification contains requirements for biocompatibility testing.

X1.2 Tissue expanders are intended to be inflated *in situ*, at intraimplant pressures sufficient to stretch soft tissue. Such stretching may also include the envelope or shell of the tissue expander, since it is reasonable to expect that expanders may be inflated beyond their normal volume in normal usage. To minimize the potential for leakage or deflation during use, this specification contains requirements for the physical properties of materials of construction, bonded or adhered areas and connectors.

X1.3 When expansion is accomplished by percutaneous hypodermic needle penetration of the tissue expander's injection port, multiple injections are typically required, spaced over a variable time period, in order to achieve adequate expansion. Thus, this specification contains requirements for resistance of the injection port to leakage after repeated needle punctures.

X1.4 The tissue expanders subject to this specification may reasonably be expected to vary widely in shape, size, and design. Tissue expander devices may vary significantly in design and the materials of construction to achieve their intended purpose. Thus, this specification contains requirements for labelling that includes defining the specific nature and function of the expander, and other appropriate use information.

X1.5 Because device sterility is an important consideration, this specification requires labelling to comply with AMI, PDA, and GMP requirements set forth by the FDA regarding sterilization.

X1.6 Methodology and criteria for tear resistance testing is not considered relevant and therefore not provided in this specification for finished devices. A propagating nick is required to measure this property, although in practice, a nick would cause incipient and catastrophic failure of the device due to deflation. Tear resistance testing in accordance with Test Method D624 is suggested, however, for characterization of the raw materials used in the construction of tissue expander devices consistent with vendor material specifications.

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