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

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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F1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices (Withdrawn 2012)[3]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

[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] 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.

and Depyrogenation[7]

3. Terminology

3.1 *Definitions:*

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-the-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 devices in intended applications. When new information becomes available or changes in state-of-the-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.

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

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

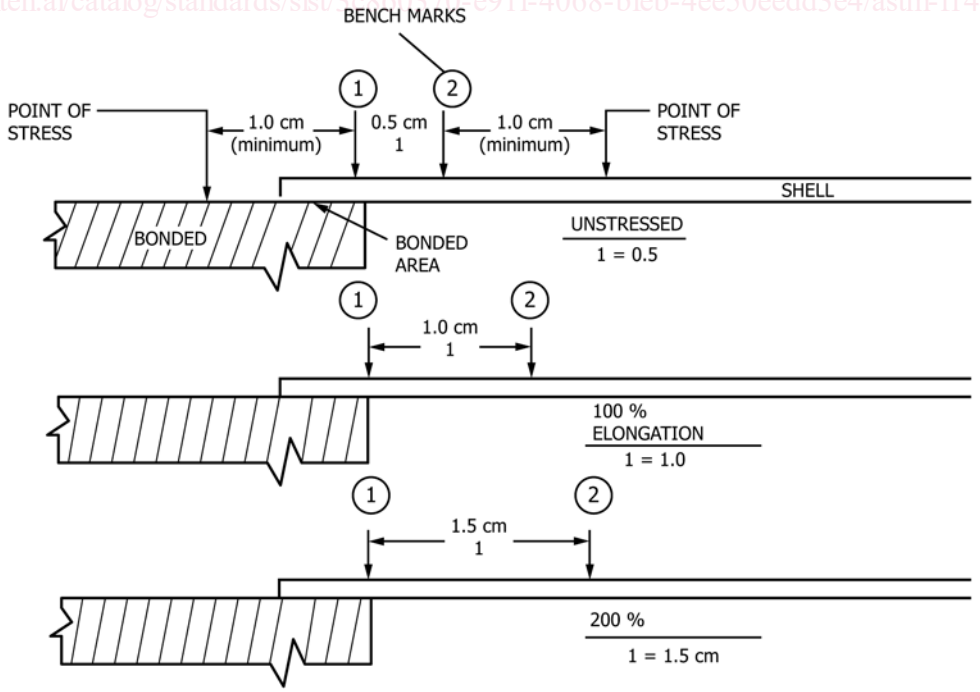

FIG. 1 Testing Fused or Adhered Joints