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Standard Specification for Soft-Tissue Expander Devices[1]

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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:*

D 412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension[2]

D 624 Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers[2]

D 1349 Practice for Rubber—Standard Temperatures for Testing[2]

F 703 Specification for Implantable Breast Prostheses[3]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[3]

F 1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices[3]

F 2038 Guide for Silicone Elastomers, Gels and Foams Used in Medical Applications Part I—Formulations and Uncured Materials[3]

F 2042 Guide for Silicone Elastomers, Gels, and Foams Used in Medical Application Part II—Crosslinking and Fabrication[3]

F 2051 Specification for Implantable Saline Filled Breast Prosthesis[3]

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/ST50-1995, Dry Heat (Heated Air) Sterilizers[6]

ANSI/AAMI/ISO 11135-1994, Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization[6]

ANSI/AAMI/ISO 11137-1994, Sterilization of Health Care Products—Requirements for Validation and Routine and Routine Control—Radiation Sterilization[6]

ANSI/AAMI/ISO 11134-1993, 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:*

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.

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[2] *Annual Book of ASTM Standards*, Vol 09.01.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

[4] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.

[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.

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

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®) 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 F 1251.

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 F 703, as applicable.

4.3.2 *Saline Only*—Expansion indications for devices of this type shall confirm to this specification in addition to Specification F 2051, 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 F 748*—New or existing materials shall be in compliance with Practice F 748 or other accepted standards such as ANSI/AAMI/ISO 10993-1. Assays recommended by Practice F 748 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 F 748 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