



Designation: F 1441 – 92 (Reapproved 2002)

## Standard Specification for Soft-Tissue Expander Devices<sup>1</sup>

This standard is issued under the fixed designation F 1441; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

### 1. Scope

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

1.2 *Limitations*—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.

1.3 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 portion, Section 7, of this specification. *This standard does not purport to address all of the safety problems, 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<sup>2</sup>

D 624 Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers<sup>2</sup>

D 1349 Practice for Rubber—Standard Temperatures for Testing<sup>2</sup>

F 604 Specification for Silicon Elastomers Used in Medical Applications<sup>3</sup>

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices<sup>3</sup>

F 1251 Terminology Relating to Polymeric Biomaterials in Medical and Surgical Devices<sup>3</sup>

#### 2.2 Federal Register:

Title 21, Part 820<sup>4</sup>

### 3. Terminology

#### 3.1 Definitions:

<sup>1</sup> 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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<sup>2</sup> *Annual Book of ASTM Standards*, Vol 09.01.

<sup>3</sup> *Annual Book of ASTM Standards*, Vol 13.01.

<sup>4</sup> Available from U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.

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 *reinforced silicone elastomer*—a composite of silicone elastomer and an embedded textile made from polyethylene terephthalate (Dacron<sup>®</sup>) fibres.

3.1.5 *shell*—an outer sac of the device which is comprised of silicone elastomer (or other appropriate material).

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

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

3.2 For other terms used in this specification see Terminology F 1251.<sup>(2)</sup>

### 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.

### 5. Significance and Use

5.1 The devices described in this specification are intended for use in soft tissue expansion. This specification identifies those factors felt to be important to ensure safety as it relates to the device biocompatibility and the mechanical integrity of the device components.


### 6. Requirements

#### 6.1 Biocompatibility:

6.1.1 Biological testing to ensure safety of soft tissue expander devices shall be selected and conducted in accordance with Practice F 748.

6.1.2 In addition to biological testing as recommended by Practice F 748, other biological testing may be appropriate.

#### 6.2 Physical Properties:

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6.2.1 *Tensile Set*—Maximum set shall be less than 10 % when tested in accordance with 7.2.1.

6.2.2 *Breaking Force*—Ultimate breaking force in tension shall be no less than 11.12 N (2.5 lb) when tested in accordance with 7.2.3.

6.2.3 *Tear Resistance*—Tear resistance shall be 3.5584 N (0.8 lb) minimum when tested in accordance with 7.2.3.

## 7. Test Methods

7.1 Tissue expander or component designs, or both, shall demonstrate an acceptable response to the following tests. Unless otherwise specified, the standard temperature for testing shall be  $23 \pm 2^\circ\text{C}$  ( $73.4 \pm 3.6^\circ\text{F}$ ). Condition the test specimens for at least 3 h when the test temperature is  $23 \pm 2^\circ\text{C}$ . If the material is affected by moisture, maintain the relative humidity at  $50 \pm 5\%$  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 D 1349.

7.2 *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.

7.2.1 *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 D 412 with the exception of sample thickness and cycle time.

7.2.2 *Breaking Force*—Test ultimate breaking force in tension in accordance with Test Methods D 412, Die C with the exception of sample thickness.

7.2.3 *Tear Resistance*—Test tear resistance in accordance with Test Method D 624, Die B or Die C with the exception of sample thickness. Include the indication of which die (B or C) is appropriate when citing tear resistance values.

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

7.3.1 *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.

7.3.2 *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.

7.4 *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  $1\text{ mm}^2$  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.

7.4.1 *21 Gage Port*—An injection port may be labelled a 21G port only if it passes the injection port competence test when tested with a 21G hypodermic needle.

7.4.2 *23 Gage Port*—An injection port may be labelled a 23G port only if it passes the injection port competence test when tested with a 23G hypodermic needle.

7.4.3 *25 Gage Port*—An injection port may be labelled a 25G port only if it passes the injection port competence test

when tested with a 25G hypodermic needle.

7.5 *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.

7.6 *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.

7.7 *Needle Stop Penetration*—Mount a 38.1-mm (1.5-in.) 21-gage hypodermic needle<sup>5</sup> 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.

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

7.8.1 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).

7.8.2 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, valve covers, etc.) shall not fail when the shell adjacent to the joint is stressed to 100 % elongation for 10 s (see Fig. 1).

## 8. Sterilization

8.1 The units may be supplied pre-sterilized in accordance with current USP<sup>6</sup> procedures and good manufacturing practices (GMP established by the FDA).

8.2 If re-sterilization of the device is intended, instruction for cleaning and sterilization shall be supplied with the package insert.

## 9. Packaging, Labelling, and Package Inserts

9.1 *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.

9.2 *Labelling*:

9.2.1 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:

9.2.1.1 Product name,

9.2.1.2 Configuration or type,

9.2.1.3 Manufacturer's name and address,

9.2.1.4 Manufacturer lot number,

9.2.1.5 Volume or dimension,

9.2.1.6 Date of sterilization or packaging (year), and

9.2.1.7 Special storage requirements, if any.

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

<sup>5</sup> Available from U.S. Pharmacopeia, Vol XX, Mack Publishing Co., Easton, PA.

<sup>6</sup> The Precision Gliide hypodermic needle, available from Becton Dickinson, One Becton Drive, Franklin Lakes, NJ 07417, or its equivalent, has been found satisfactory for this purpose.