Designation: F 1441 – 92 (Reapproved 1998)

AMERICAN SOCIETY FOR TESTING AND MATERIALS
100 Barr Harbor Dr., West Conshohocken, PA 19428
Reprinted from the Annual Book of ASTM Standards. Copyright ASTM

# Standard Specification for Soft-Tissue Expander Devices[1]

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 (ε) 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 Rubber Properties in Tension[2]

D 624 Test Method for Rubber Property—Tear Resistance[2]

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

F 604 Classification for Silicon Elastomers Used in Medical Applications[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]

2.2 *Federal Register:*

Title 21, Part 820[4]

## 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 *reinforced silicone elastomer*—a composite of silicone elastomer and an embedded textile made from polyethylene terephthalate (Dacron®) 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.

## 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*:

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

---

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.06 on Plastic and Reconstructive Surgery.

Current edition approved Dec. 15, 1992. Published February 1993.

[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, Washington, DC 20402.

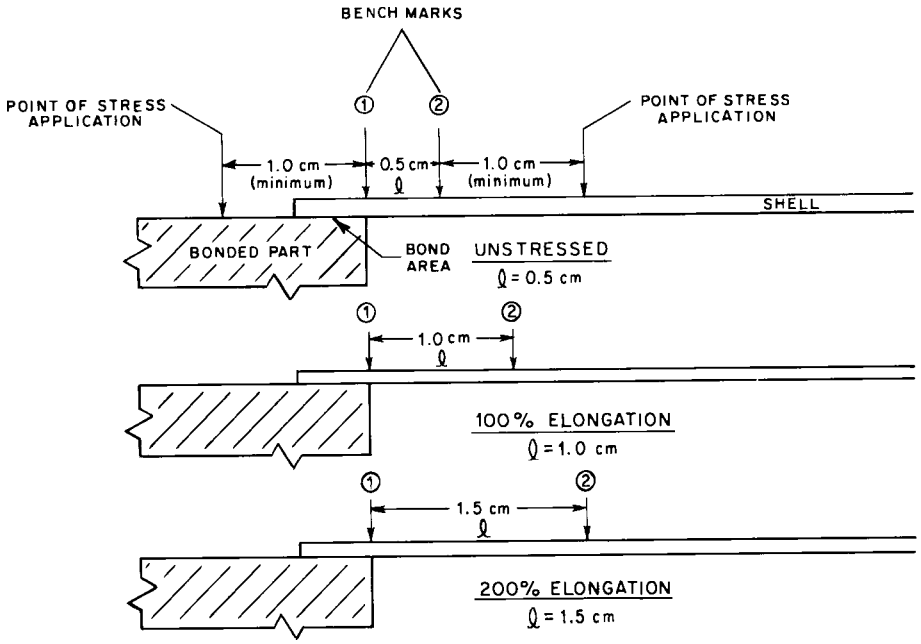


**FIG. 1 Testing Fused or Adhered Joints**

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 ± 2°C (73.4 ± 3.6°F). Condition the test specimens for at least 3 h when the test temperature is 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 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 $mm^2$ 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[5] 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[6] 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.

[5] Available from *U.S. Pharmacopeia*, Vol XX, Mack Publishing Co., Easton, PA.

[6] The Precision Glide hypodermic needle, available from Becton Dickinson, One Becton Drive, Franklin Lakes, NJ 07417, or its equivalent, has been found satisfactory for this purpose.

## 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 shall include the following information:

9.2.2.1 Product name and manufacturer,

9.2.2.2 Product lot number, and

9.2.2.3 Product type and volume dimension.

9.3 *Package Insert*—The package insert shall provide recommended instructions for use.

## 10. Keywords

10.1 elastomer; implant; implant material; medicale device; plastic surgery; soft tissue

## 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 assure 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 GMP requirements set forth by the FDA regarding sterilization.

**F 1441**

*The American Society for Testing and Materials takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.*

*This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, 100 Barr Harbor Drive, West Conshohocken, PA 19428.*