Tissue expanders are for single use only. Do not reutilize. A device is reused against the manufacturer’s recommendation. The incidence of extrusion of either tissue expander has been shown to increase when placed in injured areas: scarred, heavily irradiated or burned tissue, crushed bone areas or where severe surgical reduction of the area has occurred. The use of a tissue expander in any of these conditions is not recommended as the risk of extrusion will increase. Subsequent deflation and/or rupture will result. All expanders should be carefully inspected for structural integrity prior to and during implantation. The devices are not intended for use beyond six months.

Leakage from the injection dome can result from the use of an improper size of injection needle, injections outside the injection dome ring or excessive pressure on the overlying tissue at the tissue expander site, resulting in improper fill. Injections should be made only into the top of the injection dome, perpendicular to ±30° to the base and within the injection dome.

WARNINGs

It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the possible complications associated with the use of these products.

1. Allergenic, Toxic

2. Do not use these tissue expanders in patients that have a previously implanted device that could be affected by the magnetic fields of the injectors. Do not use this device on or near the injection dome. Magnetic fields may still occur.

3. Patients with cardiac pacemakers and a history of allergic reactions to nickel or metal, or who have a pacemaker generator that is not shielded from external magnetic fields, should not receive this device.

4. The incidence of extrusion of either tissue expander has been shown to increase when placed in injured areas: scarred, heavily irradiated or burned tissue, crushed bone areas or where severe surgical reduction of the area has occurred. The use of a tissue expander in any of these conditions is not recommended as the risk of extrusion will increase. Subsequent deflation and/or rupture will result. All expanders should be carefully inspected for structural integrity prior to and during implantation. The devices are not intended for use beyond six months.

5. These tissue expanders are not to be used in any neonatal patients.

6. Avoid Damage During Surgery

• Do not tamper with the design, configuration, style and fill volume of the device. Do not attempt to alter the device in any way.
• Do not attempt to alter the device in any way.
• Do not alter the design, configuration, style and fill volume of the device.
• Do not tamper with any of the device’s components.
• Do not attempt to alter the device in any way.
• Do not attempt to alter the device in any way.

7. Patch area

• Patch area

8. Suturing Safety

• Take care when suturing the device into place. Avoid puncturing the tissue expander’s shell during implantation using a needle or stab incision.
• Take care when suturing the device into place. Avoid puncturing the tissue expander’s shell during implantation using a needle or stab incision.

9. Magnetic Fields

• Mentor has not tested the magnetic properties of these tissue expanders. The effects of magnetic fields on these products are not known.
• Magnetic Fields

10. Use of Magnetic Field

• It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the possible complications associated with the use of these products.

11. Use of Magnetic Field

• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.

12. Intracapsular Injection

• Leakage from the injection dome can result from the use of an improper size of injection needle, injections outside the injection dome ring or excessive pressure on the overlying tissue at the tissue expander site, resulting in improper fill. Injections should be made only into the top of the injection dome, perpendicular to ±30° to the base and within the injection dome.

13. In Vivo Effects of Radiation Therapy

• The incidence of extrusion of either tissue expander has been shown to increase when placed in injured areas: scarred, heavily irradiated or burned tissue, crushed bone areas or where severe surgical reduction of the area has occurred. The use of a tissue expander in any of these conditions is not recommended as the risk of extrusion will increase. Subsequent deflation and/or rupture will result. All expanders should be carefully inspected for structural integrity prior to and during implantation. The devices are not intended for use beyond six months.

14. External Shielding

• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.

15. Contraindications

• These devices are for temporary use only.
• These devices are for temporary use only.
• These devices are for temporary use only.

16. Precautions

• Patients should be advised to maintain appropriate body weight prior to surgery.
• Patients should be advised to maintain appropriate body weight prior to surgery.
• Patients should be advised to maintain appropriate body weight prior to surgery.

17. Special Warning

• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.

18. Indications

• Avoid using or injecting saline into a tissue expander, a single-use, sterile saline container is recommended.
• Avoid using or injecting saline into a tissue expander, a single-use, sterile saline container is recommended.
• Avoid using or injecting saline into a tissue expander, a single-use, sterile saline container is recommended.

19. Literature references are available upon request from:

20. For product information or to order directly, please contact your local Mentor representative.

21. PRODUCT ORDER INFORMATION

Please do not hesitate to contact your local Mentor representative.

22. Mentor Medical Services

For more information, write to: Mentor Medical Services, Libra Corporation, 11101 Medical Drive, Irvine, CA 92618 USA

23. Identifications of the injection dome site can be accomplished by use of the CENTERSCOPE Magnetic Port Locator provided with the device. The CENTERSCOPE Magnetic Port Locator is activated by a CENTERSCOPE Magnetic Locator (sold separately) or a CENTERSCOPE Magnetic Locator placed in a groove of the device. The devices are not designed to be used on the anterior chestwall.

24. Applications

• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.

25. Design

• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.

26. Warning

• Use only a 21 gauge or smaller needle when adding or withdrawing fluid from the device to sale by or on the order of a physician or properly licensed practitioner. 102986-001Rev D Effective January 2016

27. Additional Warning

• This tissue expander is not intended for use in a patient who is being treated for a malignancy.
• This tissue expander is not intended for use in a patient who is being treated for a malignancy.
• This tissue expander is not intended for use in a patient who is being treated for a malignancy.

28. Product Information

• The devices are not intended for use beyond six months.
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29. Precaution

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• The devices are not intended for use beyond six months.

30. Indications

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• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.

31. Use of Sterilization

• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.

32. Reuse

• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.

33. Instructions for Use

• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.

34. Magnetic Field

• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.

35.von Mises Stress

• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.
• The devices are not intended for use beyond six months.

36. Introduction

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37. Safety

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51. Use of Magnetic Field

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**Fluid Accumulation**

Dissatisfaction with cosmetic results

Capsule formation and contracture

- Excessive post-operative fluid accumulation and transient reaccumulation of fluid around the tissue expander as a result of movement of the tissue expander in the pocket.
- Pain: Pain may be felt for varying degrees (severity) and duration (length of time) during the tissue expansion process.
- Hematoma: Hematoma may form when an air-filled tissue expander is inflated过多血液

- **Sterilization**

RECORDING PROCEDURE FOR TISSUE EXPANDERS

BREAST IMPLANT SURGERY: POTENTIAL ADVERSE EVENTS

- **Pain**
- **Hematoma**
- **Seroma**
- **Infection**
- **Ectopic implantation**
- **Skin necrosis or sloughing**
- **Trauma**
- **Expander shell damage**
- **Fracture**
- **Edema**
- **Hypersensitivity**
- **Friction burns**
- **Intracapsular fluid accumulation**
- **Capsule formation**

**Pre-operative Assessment**

- **Expander Selection**
- **Implantation Site**
- **Incision Size**

**Expander Expansion**

5. Fill volumes during each fill session, intervals between filling sessions, and date of explant should be indicated on the label.

REVIEWED BY:

- **Center Hospital Surgery**
- **Reconstructive Surgery**

**Suture**

- **Adhesive**
- **Sterile**
- **Surgical**

**Tissue Thinness or Necrosis**

- **Thin or thick tissue**
- **Necrosis**
- **Cancer**

**Infection**

- **Aseptic**
- **Bacterial**
- **Viral**

**Capsule Formation**

- **Capsule Size**
- **Capsule Formation**
- **Capsule Thickness**

**Mammoplasty**

- **Reduction**
- **Augmentation**
- **Revision**
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<th>STOCK</th>
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<td>BREAST TISSUE EXPANDERS</td>
<td>LAB100197243v4</td>
<td>N/A</td>
<td>N/A</td>
<td>50# White Offset</td>
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<th>SEALING METHOD</th>
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<td>EN</td>
<td>X</td>
<td>0</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

**BLEED SIZE**: 5” (12.7 mm) .325” (8.25 mm) NONE BLEED ALL SIDES BLEED TOP BLEED RIGHT BLEED LEFT BLEED BOTTOM

**DRAWING IS NOT TO SCALE**: DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK.

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