STERILE UNLESS OPENED OR DAMAGED

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Single Use Only

Item #00-321 Revised 11-01-13
Attention Physician

IMPORTANT MEDICAL INFORMATION

XPANSION® Micro-Autografting Kit
For Split-Thickness Skin Grafting

OUTLINE:
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GENERAL PRODUCT INFORMATION
A. DESCRIPTION AND INDICATIONS
B. WARNINGS AND PRECAUTIONS
C. DIRECTIONS FOR USE
D. PROTOCOL FOR XPANSION MICRO-AUTOGRAFTING KIT

DEFINITIONS
Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Batch</td>
</tr>
<tr>
<td>REF</td>
<td>Catalog number</td>
</tr>
<tr>
<td>🍍️</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>Expires</td>
<td>Date of expiration</td>
</tr>
<tr>
<td>☀️</td>
<td>Keep away from sunlight</td>
</tr>
<tr>
<td>🍃️</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🌟</td>
<td>Single Use - Do not reuse</td>
</tr>
<tr>
<td>🚫</td>
<td>Sterile unless opened or damaged</td>
</tr>
<tr>
<td>Sterile</td>
<td>R</td>
</tr>
<tr>
<td>🍃️</td>
<td>Store in dry place</td>
</tr>
</tbody>
</table>

GENERAL PRODUCT INFORMATION

A. DESCRIPTION AND INDICATIONS
The XPANSION micro-autografting kit consists of single-use, disposable instruments designed to be used for the harvesting, mechanical preparation, and application of split-thickness skin autografts for the purpose of transplantation onto wounds. This product is provided sterile for single patient use.

B. WARNINGS AND PRECAUTIONS
Proper surgical techniques are the responsibility of the medical professional. The XPANSION micro-autografting kit provides tools to facilitate the harvesting, mechanical preparation, and the application of split thickness autografts. Each physician must evaluate the appropriateness of the instruments and techniques for each patient based on his or her own medical training and expertise. As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. Every patient is different and results may vary. Donor tissue should not be taken if site is infected.

The thickness of the autograft skin harvested is pressure-dependent. When harvesting the skin graft with the dermatome, only gentle pressure into the flesh is generally needed to harvest a graft 0.012 – 0.016 inches thick. Excessive pressure could result in a donor site wound substantially deeper than necessary. Additionally, an extremely thick graft will be difficult to process effectively.

The kit is provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. The XPANSION micro-autografting kit is disposable and intended for single use only. Re-sterilization or reuse of these instruments may potentially result in serious patient harm. Examples of hazards related to the reuse of these instruments include, but are not limited to: significant degradation in device performance, cross-infection, and contamination. Immediately dispose of kit and instruments after procedure.
C. DIRECTIONS FOR USE

Each instrument is single-use disposable.

Dermatome  Forceps  Cutting Mat

Syringe  XPANSION Mincer  Spatula

1. Harvest autograft with dermatome being advanced in a sawing motion perpendicular to the direction of the harvest using gentle pressure on the surgically prepped skin. Do not push the blade forward, let it advance naturally. The length of the graft should be no larger than a postage stamp and preferably taken from the lateral side of the thigh.

2. Transfer graft to cutting mat, dermal side down is preferable to maximize friction with cutting surface.

3. Lightly moisten graft with sterile saline. Do not flood graft.

4. Open XPANSION mincer handles. Grasp XPANSION mincer with thumbs in thumb grooves and align graft through viewing window.

5. Applying even thumb pressure on both handles, pass XPANSION mincer over graft to create a number of thin strips.

6. Turn cutting mat 90° and repeat XPANSION mincer pass until all strips have been cut into small square pieces.

7. Graft is now processed into small square pieces and can be transferred from cutting mat to the wound using the spatula.

8. Transfer skin pieces from cutting mat to clean, prepared wound bed, and spread skin pieces as evenly as possible.

NOTE: ORIENTATION OF THE GRAFT PIECES DOES NOT AFFECT SUCCESS OF TRANSPLANT.
1. Wound bed preparation
   • Key to success.
   • Necrotic, nonviable tissue, debris, and slough must be removed.
   • No active bleeding.
   • Tissue bacteria level must be minimized, ideally $10^5$ or fewer bacteria per gram of tissue.

2. Surgical technique
   • Donor site must have hair removed, be surgically prepped, and anesthetized.
   • Graft is harvested with dermatome using a sawing motion. Dermatome should only be advanced in a sawing motion perpendicular to the direction of the harvest.
   • No greater than a postage stamp size graft should be taken.
   • Graft is minced in both directions after adding saline.
   • Minced graft is transferred and evenly spread on recipient wound with spatula.

3. Postoperative care
   • Non-adherent perforated dressing (e.g. bridal veil or Mepitel®) as contact layer. Secure non-adherent dressing to wound with Steri-Strips™.
   • Maintain a moist environment (e.g. light hydrogel or moisture retentive dressing).
   • Splint or immobilize if in mobile area.
   • Donor site should be cleaned with Vashe® Wound Solution and then covered with dressing.
   • Outer dressing can be changed 5-7 days leaving contact layer intact.
   • Vashe irrigation and/or soak can be used at dressing changes.
   • Contact dressing can be gently teased off graft at 10-14 days using saline irrigation to prevent any dressing adherence.