**Product Insert**

**Description:** PROKERA® SLIM is a self-retaining biologic corneal bandage. It is comprised of a cryopreserved amniotic membrane graft fastened to an ophthalmic conformer. The amniotic membrane consists of an inner ring and outer ring that serves to maintain space in the orbital cavity and to prevent lid adhesion to the ocular surface. Placement of the conformer also enables application of the cryopreserved amniotic membrane to the ocular surface without the need for sutures.

**Indications:** PROKERA SLIM is intended for use in eyes in which ocular surface cells are damaged or underlying stroma is inflamed or scarred and suited for patient comfort. Acting as a self-retaining biologic corneal bandage, PROKERA SLIM effectively treats superficial corneal surface diseases by suppressing inflammation and related pain, promoting epithelial healing, and avoiding haze.

**Precautions:**
- Do not use PROKERA SLIM if the device or packaging is damaged – contact Bio-Tissue.
- Do not use PROKERA SLIM if the patient cannot close the eyelid, has an incomplete blink or demonstrates any other signs of discomfort.
- Be sure to reduce the possibility of graft rejection, while retaining the natural biologic properties.

**Microbial testing:** Has also been performed on the final product to ensure no growth of aerobic, anaerobic or fungal cultures.

**Location & Temperature Use After Receipt**

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Description</th>
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<tbody>
<tr>
<td>-80°C → -4°C</td>
<td>Example: ultra-low temperature freezer, standard freezer, or standard refrigerator</td>
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**Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)**

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**Donor Eligibility and Summary of Records:**

- This tissue was procured from a donor determined to be eligible based on the results of screening and testing, Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/P) donor eligibility and placentia suitability, which is based on the results of donor screening at delivery for infectious, malignant, neurological & auto-immune diseases and for other exposures or social habits, has been determined and documented by TissueTech, Inc.
- A blood specimen, drawn within ±7 days of donation, has undergone serological testing by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).
- This tissue has been deemed eligible for transplantation based on acceptable screening, serological and microbial test results.
- A Certificate of Compliance regarding the manufacturing, storage, shipping and tracking controls for Bio-Tissue, Inc. products is available upon request.

**Indications:**
- Hepatitis C Antibody (HCVAb)
- Hepatitis B Core Antibody (HBcAb)
- Hepatitis B Surface Antigen (HBsAg)
- HTLV I & II Antibody (HTLV I/II Ab)
- West Nile Virus (WNV, RNA-NAT)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis C Virus (HCV, RNA-NAT)
- Hepatitis B Core (HBcAb)
- Hepatitis B (HBV, DNA-NAT)
- Microbial testing has also been performed on the final product to ensure no growth of aerobic, anaerobic or fungal cultures.

**End-User Clinician to maintain tissue intended for transplant in appropriate storage conditions**

- It is imperative that the device is stored properly until use. For proper storage instructions refer to the Storage section.
- If the patient cannot close the eyelid, has an incomplete blink or demonstrates any other signs of discomfort, address these clinical issues before or at the same time of placing PROKERA SLIM.
- If the patient cannot tolerate wearing PROKERA SLIM, the device should be removed.

**Storage:**
- It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain tissue intended for transplant in appropriate storage conditions prior to further distribution or transplantation.

Upon receipt, ensure the shipper is within the validated time indicated on the shipper. Remove the tissue and store accordingly until use.

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**Use After Receipt**

- Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)
Insertion and Removal Instructions:

- If frozen, allow PROKERA SLIM to sit at controlled room temperature (20°C - 25°C) in its original unopened packaging for at least 5 minutes.
- Peel open the lid and handle the tray using aseptic techniques.
- Discard the storage media contained within the tray.
- Thoroughly rinse PROKERA SLIM with saline solution while inside the tray to remove the storage media.
- Remove the center retainer piece from the tray to access the PROKERA SLIM.
- Patient may experience a temporary foreign body sensation upon insertion.
- Advise patient to minimize contact with eye once PROKERA SLIM is placed on the ocular surface.

**Insertion**

1. **Apply topical anesthesia**
2. **Hold the upper eyelid**
3. **Ask the patient to look down**
4. **Insert the PROKERA SLIM into the superior fornix**
5. **Pull lower eyelid down and slide PROKERA SLIM under the lower eyelid**
6. **Check centration under the slit lamp**
7. **Apply a tape-tarsorrhaphy over the lid crease (as needed)**
   - **Apply appropriate medications (as needed)**

**Removal**

1. **Apply topical anesthesia**
2. **Pull the lower eyelid down**
3. **Lift lower edge of PROKERA SLIM using a cotton swab or blunt forceps**
4. **Ask the patient to look down**
5. **Apply gentle pressure on the upper eyelid**
6. **Slide the PROKERA SLIM out**
   - **Apply appropriate medications (as needed)**

- Upon dissolution of membrane or completion of treatment, remove PROKERA SLIM.
- Do not leave in the eye longer than 29 days.

Recipient Records:

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain records for the purpose of tracing tissue post-transplantation. The responsible entity should document the disposition (transplanted or discarded) on the Donor and Recipient Information card (DRI), attach one of the provided PROKERA SLIM tracking labels to the DRI, and mail to Bio-Tissue, Inc. Attach the remaining labels in patient and hospital records. An additional DRI should be provided to the customer in the event that they need to communicate an address change to the manufacturer.

Customer Feedback:

Report any customer feedback, including complaint, error, or accident notification promptly to your local tissue provider or directly to Bio-Tissue, Inc. at (888) 296-8858 or (305) 412-4430.

For Adverse Events, complete the following section. Notify via:

Phone: (888) 296-8858 or (305) 412-4430
Fax: (305) 675-3262
Email: Customerfeedback@biotissue.com

Serial Number: __________
Expiration Date: __________
Doctor Name: __________
Facility Name: __________
Transplant Date: __________
Diagnosis/Procedure: __________
Site of Use: __________
Point of Contact’s Name: __________
Point of Contact’s Phone Number: __________
Date Adverse Event was Reported: __________
Type of Adverse Event: Microbial Infection □ Transmission of Viral Disease □ Other □
Describe the Adverse Event/Reaction __________

La version française de cette notice est disponible à www.biotissue.com.

Manufactured for Bio-Tissue, Inc. by TissueTech, Inc.
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