**Warnings:**
- Do not use PROKERA SLIM if the device or packaging is damaged – contact Bio-Tissue immediately if there is any abnormality observed (e.g. device, labeling, shipping, missing information, etc.). Refer to the Customer Feedback section for reporting.
- Do not sterilize or autoclave the product before use.
- Handle PROKERA SLIM with care during insertion.
- Do not use on patients with a history of drug reactions to Ciprofloxacin or Amphotericin B.
- Treat infections with appropriate antibiotics.

**Contraindications:**
- PROKERA SLIM should not be used in eyes with glaucoma drainage devices or filtering bleb.
- PROKERA SLIM is not intended for use in eyes in which ocular surface cells are damaged or underlying stroma is inflamed or scarred. As with the use of any human tissue, the possibility of infectious agent transmission cannot be completely eliminated although all screening and microbial testing results for this donor were satisfactory for transplantation.

**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.
- Once the packaging is opened, PROKERA SLIM shall either be transplanted or otherwise discarded.
- Do not use PROKERA SLIM if the device or packaging is damaged – contact Bio-Tissue immediately if there is any abnormality observed (e.g. device, labeling, shipping, missing information, etc.). Refer to the Customer Feedback section for reporting.

**Expiration Date:**
- All PROKERA SLIM lots are produced and shipped with an expiration date on the outer packaging (shelf-life is 2 years from date of manufacture). PROKERA SLIM is stored in a medium of Dulbecco’s Modified Eagle Medium/Glycerol (1:1) containing 20 µg/ml Ciprofloxacin and 1.25 µg/ml Amphotericin B.
- PROKERA SLIM is intended for use in eyes in which ocular surface cells are damaged or underlying stroma is inflamed or scarred. As with the use of any human tissue, the possibility of infectious agent transmission cannot be completely eliminated although all screening and microbial testing results for this donor were satisfactory for transplantation.

**Location & Temperature**

<table>
<thead>
<tr>
<th>Use After Receipt</th>
<th>Location &amp; Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unopened insulated shipping container</td>
<td>-80°C → -4°C (Example: ultra-low temperature freezer, standard freezer, or standard refrigerator)</td>
</tr>
<tr>
<td>Within the expiration date printed on outer packaging</td>
<td>Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)</td>
</tr>
</tbody>
</table>

**Place UDI Label Here**

**For Canadian Shipments Only**

See Reverse
Adverse Events:

The FDA requires that information be supplied to the product manufacturer for mandatory reporting of adverse events. Possible significant adverse events include microbial infection and transmission of viral disease.

The doctor is responsible for immediately reporting any adverse event potentially attributable to the use of PROKERA SLIM to Bio-Tissue.

Upon dissolution of membrane or completion of treatment, remove PROKERA SLIM.

Do not leave in the eye longer than 29 days.

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 sterile saline solution while inside the tray to remove the storage media and reduce the potential stinging sensation.
- 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.

• 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.

Customer Feedback:

Within the United States: Report any customer feedback, including complaint, error or accident notification promptly to Bio-Tissue at (888) 296-8858 or (305) 412-4430.

Outside of the United States: Report feedback to your local tissue provider.

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-tarsorraphy 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

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

Manufactured for Bio-Tissue, Inc. by TissueTech, Inc. 8305 NW 27th St, Suite 101, Doral, FL 33122 USA
(888) 296-8858

Insertion

Apply topical anesthesia

1. Hold the upper eyelid
2. Ask the patient to look down

Removal

Apply topical anesthesia

1. Hold the upper eyelid
2. Ask the patient to look down

Complete the following section. Notify via:

Phone: (888) 296-8858 or (305) 412-4430
Fax: (305) 412-4429
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: ____________________

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