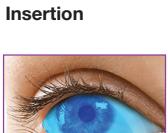
Insertion and Removal Instructions:

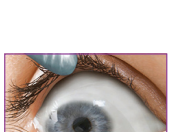
- If frozen, allow PROKERA SLIM to sit at controlled room temperature (20°C - 25°C) in its original unopened packaging for at least 5 minutes.
- Peel open the lid and handle the tray using aseptic techniques.
- Discard the storage media contained within the tray.
- Thoroughly rinse PROKERA SLIM with 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

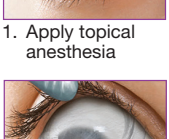


1. Apply topical anesthesia

2. Hold the upper eyelid

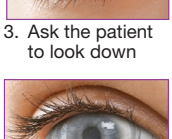


3. Ask the patient to look down

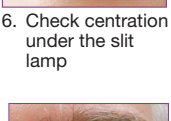


4. Insert the PROKERA SLIM into the superior fornix

5. Pull lower eyelid down and slide PROKERA SLIM under the lower eyelid

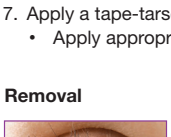


6. Check centration under the slit lamp

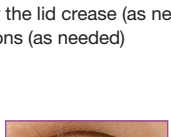


7. Apply a tape-tarsorrhaphy over the lid crease (as needed)
   - Apply appropriate medications (as needed)

Removal



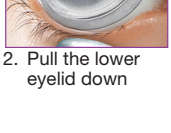
1. Apply topical anesthesia



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

- 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.

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.

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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