Use After Receipt

Within the expiration date printed on outer packaging (shelf-life is 2 years from date of manufacture) or standard freezer, or standard refrigerator. PROKERA exposed to controlled room temperature (20°C - 25°C) for up to 6 hours may be used. 

If the patient cannot tolerate wearing PROKERA, the device should be removed. If the patient cannot close the eyelid, has an incomplete blink or demonstrates any other signs of exposure, address these clinical issues before or at the same time of placing PROKERA. 

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 exposure, address these clinical issues before or at the same time of placing PROKERA. 

If the patient cannot tolerate wearing PROKERA, the device should be removed. 

Place UDI Label Here
For Canadian Shipments Only

Location & Temperature Use After Receipt

Unopened insulated shipping container Within the expiration date printed on outer shipping box

-80°C → 4°C
(-112°F → 39.2°F)

Example: ultra-low temperature freezer, standard freezer, or standard refrigerator

Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)

ProKera® is for single-use only in one patient by an ophthalmologist or optometrist. 

Contraindications:

• PROKERA should not be used in eyes with glaucoma drainage devices or filtering bleb.

Precautions:

• Do not use PROKERA if the device or packaging is damaged – contact Bio-Tissue immediately.

• Do not sterilize or autoclave the product before use.

• Once the packaging is opened, PROKERA shall either be transplanted or otherwise discarded.

• If there is any abnormality observed (e.g. device, labeling, shipping, missing information, etc.). 

• Do not use PROKERA if the device or packaging is damaged – contact Bio-Tissue immediately.

Donor Eligibility and Summary of Records:

This tissue was procured from a donor determined to be suitable based on the results of screening and testing, Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/P) donor eligibility and placenta 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. 

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 non-reactive. 

Microbial testing has also been performed on the final product to ensure no growth of aerobic, anaerobic or fungal cultures. The cell activity in the tissue has been inactivated using our CryoTek cryopreservation process 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. 

Unopened insulated shipping container

Example: ultra-low temperature freezer, standard freezer, or standard refrigerator

Within the expiration date printed on outer shipping box

-80°C → 4°C
(-112°F → 39.2°F)

Example: ultra-low temperature freezer, standard freezer, or standard refrigerator

Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)

ProKera® is a self-retaining biologic corneal bandage. It is comprised of a cryopreserved amniotic membrane graft fastened to an ophthalmic conformer. This product is aseptically fastened to an ophthalmic conformer. This product is aseptically

PROKERA 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. 

Microbial testing has also been performed on the final product to ensure no growth of aerobic, anaerobic or fungal cultures. The cell activity in the tissue has been inactivated using our CryoTek cryopreservation process 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. The cell activity in the tissue has been inactivated using our CryoTek cryopreservation process 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. The cell activity in the tissue has been inactivated using our CryoTek cryopreservation process 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. The cell activity in the tissue has been inactivated using our CryoTek cryopreservation process 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. The cell activity in the tissue has been inactivated using our CryoTek cryopreservation process 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. The cell activity in the tissue has been inactivated using our CryoTek cryopreservation process 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. The cell activity in the tissue has been inactivated using our CryoTek cryopreservation process 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. The cell activity in the tissue has been inactivated using our CryoTek cryopreservation process 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. The cell activity in the tissue has been inactivated using our CryoTek cryopreservation process to reduce the possibility of graft rejection, while retaining the natural biologic properties.
Insertion and Removal Instructions:

- If frozen, allow PROKERA 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 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.
- Patient may experience a temporary foreign body sensation upon insertion.
- Advise patient to minimize contact with eye once PROKERA is placed on the ocular surface.

Insertion

1. Apply topical anestheisa
2. Hold the upper eyelid
3. Ask the patient to look down
4. Insert the PROKERA into the superior fornix
5. Pull lower eyelid down and slide PROKERA 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 anestheisa
2. Ask the patient to look down
3. Pull lower eyelid down
4. Apply gentle pressure on the upper eyelid
5. Slide the PROKERA out

- Upon dissolution of membrane or completion of treatment, remove PROKERA.
- Do not leave in the eye longer than 30 days.

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 to Bio-Tissue.

Complete the following section. Notify via:
Phone: (888) 296-8858 or (305) 412-4430
Fax: (305) 412-4429
Email: Customerfeedback@biotissue.com

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 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.

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 to Bio-Tissue.

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