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 processed from tissues obtained from donated human tissue (placentas) according to current Good Tissue Practices (cGTP) and Good Manufacturing Practices (cGMP) regulations established by the US Food & Drug Administration (FDA). PROKERA is a Class II medical device cleared by the FDA.

**Donor Eligibility and Summary of Records:**
- This tissue was procured from a donor determined to be eligible based on the results of donor eligibility and placenta suitability, which is based on the results of donor 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 and testing required by the US Food & Drug Administration (FDA). PROKERA is a Class II medical device cleared by the FDA.

**Description:**
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 processed from tissues obtained from donated human tissue (placentas) according to current Good Tissue Practices (cGTP) and Good Manufacturing Practices (cGMP) regulations established by the US Food & Drug Administration (FDA). PROKERA is a Class II medical device cleared by the FDA.

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

**Warnings:**
- If the patient cannot tolerate wearing PROKERA, the device should be removed.

**Precautions:**
- The possibility of infectious agent transmission cannot be completely eliminated although all screening and microbial testing results for this donor were performed for the following infectious diseases and results were non-reactive:
  - HIV-1 & HIV-2 Antibody
  - Hepatitis C Antibody (HCVAb)
  - Hepatitis C Virus (HCV, RNA-NAT)
  - Hepatitis B Surface Antigen (HBsAg)
  - Hepatitis B Core Antibody (HBcAb)
  - Hepatitis B Virus (HBV, DNA-NAT)
  - Human Immunodeficiency Virus (HIV, RNA-NAT)
  - Syphilis (RPR)
  - HTLV I & II Antibody (HTLV I/II Ab)
  - West Nile Virus (WNV, RNA-NAT)
  - Serological and microbial test results.

**Indications:**
PROKERA® is intended for use in eyes in which ocular surface cells are damaged or underlying stroma is inflamed or scarred and best suited to prevent adhesion of the eyelid to the corneal surface with the last recipient. Acting as a self-retaining biologic corneal bandage, PROKERA® effectively treats superficial corneal surface diseases by suppressing inflammation and related pain, promoting epithelial healing, and avoiding haze.

**Location & Temperature Use After Receipt**

- **-80°C to -4°C (39.2°F to 20°F)**
- **At room temperature (20°C to 25°C)**
- **4°C**

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

**Location & Temperature**

- **Storage:**
  - The tissue is procured with the last recipient.
  - The tissue has been deemed eligible for transplantation based on acceptable screening, serological and microbial test results.

- **Indications:**
  - This tissue was procured from a donor determined to be eligible based on the results of donor eligibility and placenta suitability, which is based on the results of donor 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 and testing required by the US Food & Drug Administration (FDA). PROKERA is a Class II medical device cleared by the FDA.

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**Location & Temperature**

- **Use After Receipt**
- **Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)**
• 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 and Removal Instructions:

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.

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

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.

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