CANADA

Product Insert

Description

Prokera® Plus is a self-retaining biologic corneal bandage. **Prokera Plus** is comprised of a cryopreserved amniotic membrane graft fastened to an ophthalmic conformer. **Prokera Plus** contains a double layer of cryopreserved amniotic membrane with an inner ring diameter of 15.5 mm and an outer ring diameter of 21.6 mm. **Prokera Plus** is manufactured, using the CryoTek® process, from donated human birth tissue according to Current Good Tissue Practice (CGTP) and Current Good Manufacturing Practice (CGMP) regulations established by the US Food & Drug Administration (FDA). **Prokera Plus** is stored in a solution of 1:1, v/v Dulbecco's Modified Eagle Medium (DMEM)/Glycerol containing 20 µg/ml Ciprofloxacin and 1.25 µg/ml Amphotericin B. **Prokera Plus** is a Class II medical device cleared by the FDA and a Class IV medical device licensed by Health Canada. **Prokera Plus** is for single use only in one patient by an ophthalmologist or optometrist.

Indications

- **Prokera Plus** is intended for use in eyes in which ocular surface cells are damaged or underlying stroma is inflamed or scarred and best suited for cases of incomplete blinking or eyelid exposure. Acting as a self-retaining biologic corneal bandage, **Prokera Plus** effectively treats superficial corneal surface diseases by suppressing inflammation, promoting epithelial healing, and avoiding haze.
- **Prokera Plus** is inserted between the eyeball and the eyelid to maintain space in the orbital cavity and to prevent closure or adhesions. Placement of the conformer also enables application of the cryopreserved amniotic membrane to the ocular surface without the need for sutures.

Contraindications

- **Prokera Plus** should not be used in eyes with glaucoma drainage devices or filtering blebs.

Precautions

- Do not use **Prokera Plus** if the device or packaging is damaged – Contact BioTissue immediately if there is any abnormality observed (e.g. device, labeling, shipping, missing information, etc.). Refer to the Customer Feedback section for reporting.
- **Prokera Plus** exposed to controlled room temperature (20°C to 25°C, 68°F to 77°F) for up to 6 hours may be returned to cold temperature storage in accordance with the Storage section as long as the packaging remains unopened and intact.
- Once the packaging is opened, **Prokera Plus** shall either be transplanted or otherwise discarded.
- Do not sterilize or autoclave the product before use.
- Handle **Prokera Plus** with care during insertion.

Warnings

- Do not use on patients with a history of drug reactions to Ciprofloxacin, Amphotericin B, Glycerol, and/or DMEM.
- 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.
- 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 Plus**.
- If the patient cannot tolerate wearing **Prokera Plus**, 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 transplantation in appropriate storage conditions prior to further distribution or transplant.

Upon receipt, ensure the validated time on the shipper has not expired. Remove the product and store accordingly until use.

Location & Temperature	Use After Receipt
-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)

Place UDI Label Here
For Canadian Shipments Only

Insertion and Removal Instructions

- If frozen, allow **Prokera Plus** to sit at controlled room temperature (20°C to 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 Plus** 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 Plus**.
- Spread tissue overhang outwards to cover the skirt, prior to insertion.
- Patient may experience a temporary foreign body sensation upon insertion.
- Advise patient to minimize contact with eye once **Prokera Plus** is placed on the ocular surface.

See Reverse

Prokera® Plus

Insertion

1. Apply topical anesthesia

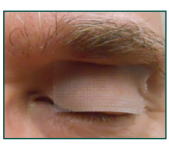
2. Hold the upper eyelid

3. Ask the patient to look down

4. Insert the **Prokera Plus** into the superior fornix

5. Pull lower eyelid down and slide **Prokera Plus** 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 Plus** 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 Plus** out

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

Donor Eligibility and Summary of Records

- This tissue was procured from a donor determined to be eligible based on the results of donor screening and testing. Donor-eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, has been performed and documented by BioTissue Holdings 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). The donor has been tested for the following infectious diseases and results were non-reactive:

— HIV-1 & HIV-2 Antibody
— HIV-1 (RNA-NAT)
— Hepatitis B Surface Antigen (HBsAg)
— Hepatitis B Core Antibody (HBcAb)
— Hepatitis B Virus (HBV, DNA-NAT)
— Hepatitis C Antibody (HCVAb)
— Hepatitis C Virus (HCV, RNA-NAT)
— Syphilis (RPR)
— HTLV I & II Antibody (HTLV I/II Ab)
— West Nile Virus (WNV, RNA-NAT)

- This tissue has been deemed eligible for transplantation based on acceptable screening, serological and microbial test results.
- Microbial testing of final product has also been performed to ensure no growth of aerobic, anaerobic or fungal cultures.
- A Certificate of Compliance regarding the manufacturing, storage, shipping and tracking controls for BioTissue products is available upon request.

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 transplanting entity should document the disposition (transplanted or discarded) on the Donor and Recipient Information Card (DRI), attach one of the provided product tracking labels to the DRI and mail to BioTissue. 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

Within the United States: Report any customer feedback, including complaint, error or accident notification promptly to BioTissue at (888) 296-8858.
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 Plus to BioTissue.**

For Adverse Events, notify via:
Website: www.biotissue.com/complaints
Phone: (888) 296-8858
Fax: (305) 675-3262
Email: Customerfeedback@biotissue.com

Scan Code

BioTissue®

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

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