

# PROKERA

U.S. Patent No. 6,152,142; 6,326,019 and 7,494,802 B2

## Product Insert

**Description:** ProKera® is a Class II medical device comprised of a cryopreserved amniotic membrane graft fastened to a thermoplastic ring-set. The cell activity in the tissue has been inactivated to eliminate the possibility of graft rejection while retaining the natural biologic properties. ProKera® is stored in a validated medium made of Dulbecco's Modified Eagle Medium/Glycerol (1:1) containing Ciprofloxacin and Amphotericin B.

### Indications:

- ProKera® is intended for use in eyes in which ocular surface cells have been damaged, or underlying stroma is inflamed or scarred. Acting as a self retaining biological bandage, ProKera® effectively treats superficial corneal surface diseases by reducing pain, suppressing inflammation, promoting epithelial healing, and avoiding haze.
- ProKera® is inserted between the eyeball and the eyelid to maintain space in the orbital cavity and to prevent closure or adhesions. Insertion of the conformer also enables application of the amniotic membrane to the ocular surface without the need for sutures.
- ProKera® is for single and prescription use only.

### Contraindications:

- ProKera® should not be used in eyes with glaucoma drainage devices or filtering bleb.

### Precautions:

- Do not use ProKera® if the packaging is damaged – Contact Bio-Tissue immediately if there is any abnormality observed in any area (e.g. labeling, packaging, shipping, missing information, etc).
- Once the outer foil pouch is opened, ProKera® should be used as soon as possible.
- Do not sterilize or re-sterilize the product. Do not autoclave before use.

### Warnings:

- 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®.
- Do not use on patients with a history of drug reactions to Ciprofloxacin or Amphotericin B.
- 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 were satisfactory for this donor.
- It is imperative that the device is stored properly until use.
- In the rare instance that the patient cannot tolerate wearing ProKera®, the device should be removed.

### Instructions:

- Allow ProKera® to thaw at room temperature in its original unopened packaging for at least 5-10 minutes.
- Open the outer foil peel pouch and aseptically present the inner clear pouch to the sterile field.
- Open the inner clear peel pouch and remove the ProKera® device using blunt forceps.
- Rinse ProKera® with sterile saline solution to reduce stinging sensation.
- Place ProKera® onto the cornea.
- After placement, complete the Donor and Recipient Information Form and return to Bio-Tissue immediately. If the tissue is discarded, please record this on the Donor and Recipient Information Form.
- Upon dissolution of membrane or completion of treatment, remove ProKera®.
- Do not leave in the eye longer than 30 days.

**Adverse Reactions:** Any adverse event potentially attributable to the use of ProKera® must be reported promptly by the physician to Bio-Tissue by completing the **Adverse Event Form** provided with the product.

Also see **Handling & Storage Instructions** and **Certificate of Analysis** provided with each shipment