

4. If temporary removal is desired, place ProKera® in sterile preservative-free pH-Balanced saline solution before re-insertion.
5. Upon completion of treatment, remove ProKera® by grabbing the conformer rim with a forceps with or without a lid speculum or lubricating eye ointment.

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.

Certificate of Quality:

Product Name: ProKera®
<u>Good Manufacturing Practice (GMP)</u> – This product was manufactured and assembled in facilities that meet FDA Medical Device GMP Standards and FDA Good Tissue Practices (GTP) Standards.
<u>ISO 9000 & ISO 13485:</u> This product's ophthalmic conformer was designed and manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9000 and ISO 13485 Quality Systems Standards.
<u>Microbiological Testing:</u> Microbiology testing performed by an independent CLIA certified lab showed that random samples of this product yielded no growth of anaerobic, aerobic or fungal organisms.
<u>Donor Screening & Infectious Disease Testing:</u> AmnioGraft® has been recovered aseptically from a donated placental membrane through elective Caesarian Section delivery. The donor was screened for infectious, malignant, neurological, and autoimmune diseases and other exposures or habits and determined to be suitable to donate membrane for human transplantation. The donor of this product was tested at the time of delivery by a CLIA certified independent laboratory and was found to be non-reactive for HIV-1 & HIV-2 (antibodies), Hepatitis B surface antigen (HBsAg), Hepatitis B core antibody (HBcAb), Hepatitis C antibody (HCV), HTLV 1 & 2 antibodies, West Nile Virus (WNV) and syphilis (RPR) using test kits licensed by the FDA.

Customer Assistance:

For end-user questions about donor or processing procedures, replacement policy or other questions regarding ProKera®, e-mail Bio-Tissue at Info@BioTissue.com or call (305) 412-4430.

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NEW Softer Ring



PROKERA®

(U.S. Patent No. 6,152,142; 6,326,019 and Patent Pending)



Product Insert

*ProKera® is designated by the US FDA (510(k) Clearance)
as a class II medical device.*

Description: ProKera® is a corneal-epithelial device consisting of a plastic ophthalmic conformer that incorporates amniotic membrane (AmnioGraft®), cryopreserved to retain the natural biological properties of the membrane. ProKera® has been processed using patented technologies in a validated storage medium made of Dulbecco's Modified Eagle Medium/Glycerol (1:1) containing Ciprofloxacin and Amphotericin B and no preservatives have been added. As part of the process, the tissue has been frozen at -80°C in order to render the cells present nonviable and eliminate the possibility of graft rejection.

Indications & Usage: ProKera® is intended for use in eyes in which ocular surface cells have been damaged, or underlying stroma is inflamed or scarred. ProKera® is used in the eye to reduce inflammation, promote healing, prevent scarring, minimize pain, and diminish the formation of abnormal blood vessels on the ocular surface. ProKera® is for single use and prescription use only.

Precautions:

- Contact Bio-Tissue immediately if the packaging is damaged.
- 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 issues before inserting 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, although all screening and microbial testing results were satisfactory for this donor, the possibility of infectious agent transmission cannot be completely eliminated.
- It is imperative that the graft is stored properly until transplantation.

Recommended Storage Before Use: After receipt, store ProKera® as follows until time of use:

Location & Temperature	Use After Receipt
Unopened Insulated Shipping Container	Within the expiration date printed on outer shipping box
Standard Refrigerator 1°C → 10°C (33.8°F → 50°F)	Within 3 months of placing in the refrigerator or until expiration date printed on outer product packaging, whichever comes first
Standard Freezer (home or general use) -49°C → 0°C (-56.2°F → 32°F)	Within 1 year of placing in the freezer or until expiration date printed on outer product packaging, whichever comes first
-80°C Freezer -85°C → -50°C (-121°F → -58°F)	Until the expiration date printed on outer product packaging (shelf-life is 2 years from date of manufacture)

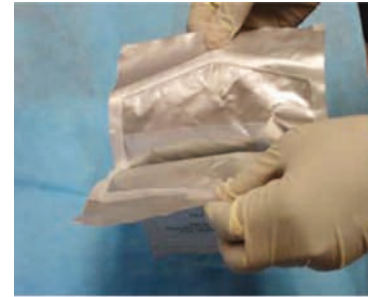
How Supplied: ProKera® is available in two sizes - 15 mm for small eyes and 16 mm for normal and large eyes. ProKera® is provided along with a Medi-PAK® Kit with sterile scissors and forceps as well as [Donor & Recipient Information](#) and [Adverse Event](#) Forms and a [Certificate of Analysis](#).

Provide the following Instructions to the Patient for ProKera® Use:

Do not wear contact lenses during ProKera® use.	Avoid rubbing, strong blinking or moving ProKera® around with fingers.
Do not drive, operate heavy machinery or perform functions that require unobstructed vision or good depth perception.	Shower only when the eye is tightly closed; Do not swim or soak face with water without appropriate protective eyewear.

Before Insertion:

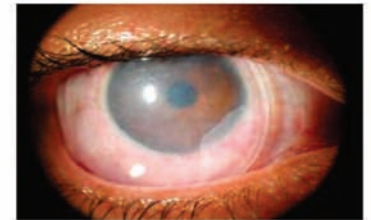
1. Always handle ProKera® using sterile/aseptic techniques.
2. Make available the following: lid speculum, gloves, anesthetic drops and antibiotic drops.
3. Thaw at room temperature for 5-10 minutes (do not use a microwave or water bath).
4. Open the outer foil peel pouch and aseptically present the inner clear pouch to the sterile field.
5. Use sterile forceps provided to grab inner package.
6. Use sterile scissors to cut inner package with enough space to remove the ProKera® device (inner package may be placed in a sterile field).



7. Use blunt forceps or fingers to grab only at the plastic rim (ProKera® membrane is slippery).
8. Avoid tearing and touching the ProKera® membrane in the center.

Insertion:

1. Place anesthetic drops in the eye.
2. Insert a lid speculum.
3. Do not trim excess membrane.
4. Insert ProKera® beneath the speculum by lifting the lid speculum.
5. Place antibiotic drops in the eye.



After Insertion & Removal:

1. Complete the [Donor & Recipient Information Form](#) and return it to Bio-Tissue immediately.
2. ProKera® can remain in the eye for up to 30 days or until the ocular surface has healed or the membrane has dissolved.
3. There is no need to remove ProKera® during fluorescein staining and Tonopen measurement of eye pressure.