



PROKERATM

Product Insert

*ProKeraTM is approved by the US FDA (510K Approval)
as a class II medical device.*

ProKera™ is a corneal-epithelial device consisting of an ophthalmic conformer that incorporates amniotic membrane (AmnioGraft™). ProKera™ is for physician use only and is not intended to be used by patients without a doctor's recommendation. ProKera™ is intended for use in eyes in which ocular surface cells have been damaged, or underlying stroma is inflamed and scarred. It can be used as a graft for ocular surface reconstruction procedures including the following:

- Corneal Diseases with Erosion
- Corneal Diseases with Superficial and Deep Ulceration
- In Conjunction with Corneal Transplantation
- Neurotrophic Corneal Diseases
- Acute Corneal or Conjunctiva Burns or Stevens Johnson Syndrome
- After Fornix or Socket Reconstruction
- Severe Corneal Inflammation

ProKera™ has been assembled so that the stromal side, the "sticky side", will be in contact with the recipient's ocular surface. ProKera™ is specially preserved in the frozen state and the natural biological/physiological properties of the membrane remain. Therefore, it can promote healing, prevent scarring, minimize pain, diminish the formation of new blood vessels and reduce inflammation on the ocular surface. ProKera™ is preserved in a validated and patented storage medium made of Dulbecco's Modified Eagle Medium and Glycerol (1:1) containing Ciprofloxacin and Amphotericin B. No preservatives or additives have been added. The device has been stored at -80 °C prior to distribution. It is imperative that the graft device is stored properly until use.

Storage Information

Usage after Receipt of Device	Storage Temperature:	Acceptable Storage Location:	Storage Time:
Few hours after package arrival	Frozen	Styrofoam shipping container	Until <u>Dry-Ice</u> expiration date on package
Within 1 week of receipt (with no freezer)	4°C (39.2°F)	Standard Home Refrigerator	1 week (media in liquid state)
Within 3 months of receipt	-20°C (-4°F)	Standard Home Freezer	3 months (media in liquid state)
Long term storage	-80°C (-112°F)	Bone Freezer	Until expiration date on package (media frozen solid)

Pre-Use Instructions

- Contact Bio-Tissue immediately for further instructions if the packaging appears to be damaged in any way, if the package contains no dry ice at the time of arrival, or if the package is expired at the time of arrival
- If packaging damage is noted, do not sterilize or re-sterilize the product
- Once outer foil pouch is opened, ProKera™ must be used immediately or discarded. If it is discarded, a record of device disposal shall be recorded on the Donor & Recipient Information Form and sent back to Bio-Tissue.
- ProKera™ may only be used by those physicians or facilities that are qualified to accept tissues and have accepted responsibility for proper handling and tissue tracking. Bio-Tissue assumes no responsibility for the clinical use of ProKera™.
- Although all screening and testing results were satisfactory for this donor, this membrane may transmit infectious agents. Microbiological testing on the membrane was acceptable. Detailed information on this device is disclosed on The Donor & Recipient Information Form and on the Certificate of Quality.

ProKera™ Sizing Information

If patient cannot close the eyelid, do not use ProKera™.

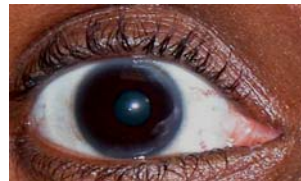
Use a 15 mm ProKera™ with Small to Medium-Sized Eyes:

**A small eye
(picture in actual size)**



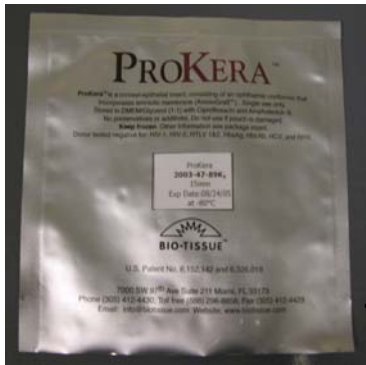
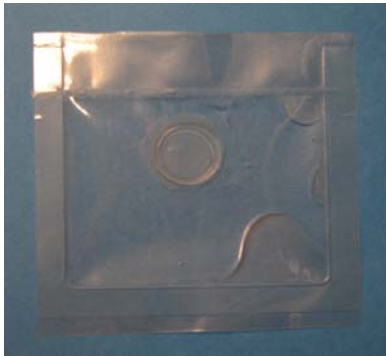
Use a Size 16 mm ProKera™ with Large Eyes:

**A large eye
(picture in actual size)**



Physician Instructions

I. General

<p>Materials Needed:</p> <ol style="list-style-type: none"> 1. Sterile lid speculum 2. Sterile gloves 3. Anesthetic drops 4. Antibiotic drops 	<p>Materials Provided:</p> <ol style="list-style-type: none"> 5. Medi-PAK® Kit with sterile scissors and forceps 6. Bio-Tissue "Donor Recipient Information" (DRI) form
<p>General Precautions:</p> <ul style="list-style-type: none"> ▪ There are several sizes of ProKera™ available. A patient's Interpalpebral width should be measured and the correct ProKera™ size should be determined using the provided sizing chart (see page 3). ▪ Immediately prior to use, thaw at room temperature for 5-10 minutes (do <u>not</u> use a microwave or water bath) ▪ Do <u>not</u> trim excess membrane ▪ Prior to use, ensure that: <ul style="list-style-type: none"> ○ There are no tears or rips in the package ○ Patient can close the eyelid (no lagophthalmos) ○ Patient is not wearing contact lenses ○ There is no patient history of drug reactions to Ciprofloxacin or Amphotericin B ▪ Do not autoclave before use ▪ Do not re-use – for single use only 	
<p>Opening Package:</p> <ol style="list-style-type: none"> 1. Open outer foil package by tearing across from the tab 	<ol style="list-style-type: none"> 2. Use sterile scissors to cut the inner package with enough space to remove the ProKera™ 

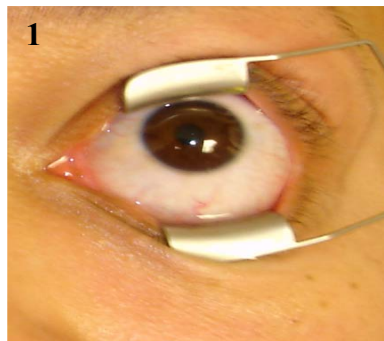
II. Pre-Insertion

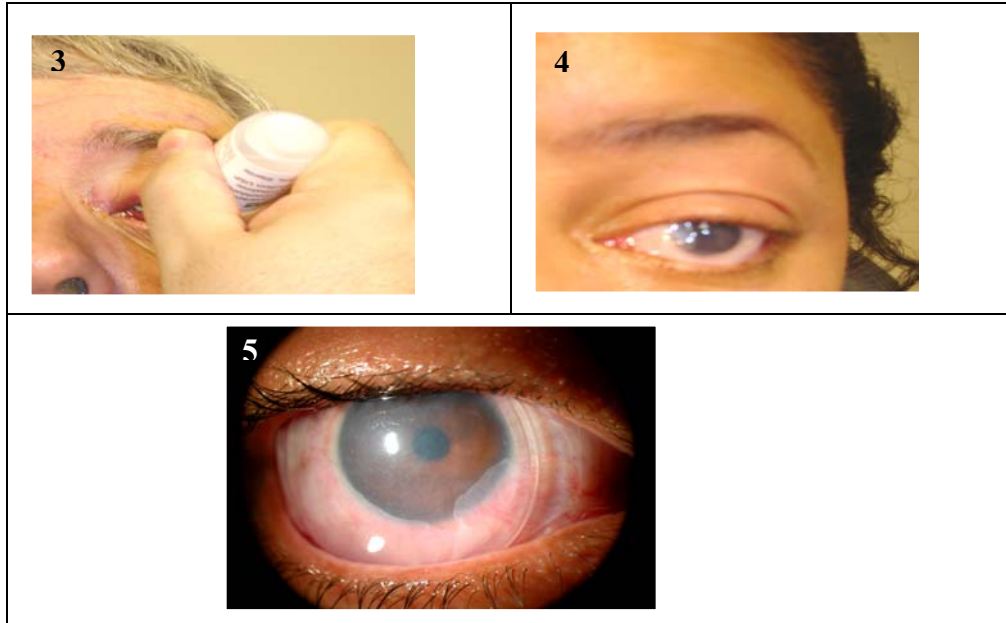
- Handle ProKera™ using sterile techniques
- Note that the ProKera™ membrane is very slippery – use sterile forceps or fingers to grasp only at the rim of the ProKera™
- Handle the membrane with care to avoid tearing and touching the membrane in the center– use blunt instruments only



III. Insertion

- Use a lid speculum to insert the ProKera™ beneath it. (pictures 1 and 2) This is accomplished by lifting the lid speculum so that the ProKera™ can rest beneath it.
- Administer anesthetic drops. (picture 3)
- Provide prophylactic antibiotic drops.
- After insertion (pictures 4 and 5), ProKera™ can remain in the eye until the ocular surface has healed or the membrane has dissolved (up to 8 weeks) during which time the healing can be assessed by fluorescein staining and eye pressure measured by Tonopen.
- Provide the patient with the "ProKera™ Patient Instructions" (see page 7).





IV. Temporary Storage

- If ProKera™ needs to be temporarily removed (for example, to check patient healing progress) it can be stored in sterile PBS until re-insertion.

V. Removal

- Upon completion of treatment, the physician should remove the ProKera™ conformer with a sterile forcep, with or without the help of a lid speculum.

VI. Post-Use Instructions

- After the insertion, the Donor & Recipient Information Form is to be filled out and returned to Bio-Tissue immediately.
- Any adverse event potentially attributable to the membrane must be reported promptly by the end-user physician to Bio-Tissue by completing the Adverse Event Form.
- If the end-user needs any additional information about the donor or processing procedures, return policy or other questions, please contact Bio-Tissue at (305) 412 -4430 or 1-888-296-8858.

VII. Patient Instructions

- Remove the attachment below and give it to patient.

ProKera™ Patient Instructions Handout

- Do not wear contact lenses during ProKera™ use.
- Avoid rubbing, strong blinking or moving ProKera™ around with your fingers.
- Do not swim or soak face with water without appropriate protective eyewear.
- Shower only when the eye is tightly closed.
- Use artificial tears or other eye drops 3-4 times daily, especially if there is a concern of dry eye or exposure.
- Do not drive, operate heavy machinery or perform functions that require unobstructed vision or good depth perception.
- Consult your physician right away if discomfort is experienced or if any other problems are encountered.

Certificate of Quality

Product Name: **ProKera™**

Good Manufacturing Practice (GMP) – This product was manufactured and assembled in facilities that meet FDA Medical Device GMP Standards and FDA Good Tissue Practices (GTP) Standards.

ISO 9000: This product's ophthalmic conformer was manufactured in a facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9000 Quality Systems Standard.

Microbiological Testing: Microbiology testing by an independent laboratory showed that random samples of this product yielded no growth of anaerobic, aerobic or fungal organisms.

Donor Screening & Infectious Disease Testing: 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 and 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, and syphilis (RPR) using test kits licensed by the FDA.

If you have further questions regarding ProKera™, please e-mail Bio-Tissue at Info@BioTissue.com or call (305) 412-4430. If you have specific technical questions regarding ProKera™, please e-mail Dr. Scheffer Tseng at stseng@ocularsurface.com or call (305) 274-1299.

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