# PROKERA®

## Patients' Guide to PROKERA®

With PROKERA, you can have peace of mind in knowing that your physician has chosen a product that can help facilitate healing<sup>1</sup> and help restore your ocular surface to a natural and healthy state.

To date, over 100,000 patients have experienced the beneficial properties of PROKERA. This guide will help you understand what you can expect during treatment with PROKERA.



"For many years, I suffered in pain from my dry eyes which eventually led to a corneal ulcer. My eyes were constantly itchy and red and my vision fluctuated. The treatment with PROKERA was quick and simple, and felt similar to a contact lens being inserted. My vision has improved, which is crucial to me as an artist. PROKERA has truly changed my quality of life and brought me back to feeling normal again."

Patient

### What is PROKERA?

PROKERA is the only medical device made from amniotic membrane for use by eye care practitioners that is recognized by the FDA<sup>2</sup> to reduce inflammation and minimize corneal scarring associated with various ocular surface diseases. PROKERA may help to restore your cornea and return your eye to a normal, healthy state.

## Is PROKERA safe?

PROKERA is a safe treatment provided by an FDA-regulated tissue bank. The donor and tissue have passed numerous quality control tests including social habits, physical and medical screening before it is provided to your doctor. The tissue is donated from healthy mothers who have had c-sections.

## **Treatment Period**

For optimal corneal healing, the treatment period is usually 3-5 days. Depending on your condition, your doctor may choose to extend it to do a second treatment. Your doctor may schedule a follow up appointment to check the progress of your treatment within 5 days after the insertion and for removal of the PROKERA device.

## Allergies and Warnings

If you are allergic to Ciprofloxacin, Amphotericin B, Glycerol, and/or DMEM, you should notify your doctor and not receive the PROKERA treatment. You may experience discomfort from the insertion of PROKERA. You should notify your doctor of any swelling, redness or discharge.

#### References

<sup>1</sup> McDonald et al. "Treatment Outcomes in the Dry Eye Amniotic Membrane (DREAM) Study." Presented at AAO Annual Meeting 2017, PO055 <sup>2</sup> Bio Tissue, Inc. Request for Designation (RED). Letter on file, 2001.

 $^{2}$  Bio-Tissue, Inc. Request for Designation (RFD), Letter on file, 2001

NOTE: For complete indications, contraindication, warnings, precautions, and adverse reactions, please reference full package insert. Copyright © 2019 TissueTech Incorporated. All rights reserved. PROKERA and Bio-Tissue are registered trademarks of TissueTech, Inc. BT-0314 Rev 03



• Have a driver bring you to the appointment.

#### Day of PROKERA Insertion

- Some patients may experience discomfort; this is usually caused by a foreign body sensation but is NOT painful.
  Your doctor may docide to use tape to partially close your evolid which cap
- Your doctor may decide to use tape to partially close your eyelid which can help to alleviate the discomfort.
  - PROKERA is not fully transparent so expect your vision to be somewhat cloudy during treatment.

• After the insertion, it is suggested you go home and take a nap, this usually helps to get over the initial discomfort stage.

• Your eye may water a lot, turn red, and exhibit discharge - all of which is normal and part of the healing process. Notify your doctor with concerns.

#### First 24 Hours after Insertion of PROKERA

• Your doctor may prescribe gel tears and/or to apply cool compresses on your closed eyelids if you are feeling discomfort. You can also take acetaminophen or ibuprofen to help with the discomfort.

• Try to point your nose at any object you want to look at as it will help minimize any additional discomfort.

• After sleeping, you may wake with matted lashes from discharge; this is also normal. Carefully dab away any discharge from your lashes with a clean wet towel.

• Do not rub your eye too hard with towel as this moves the device and could damage your cornea.

#### Your vision will appear to be cloudy and you will be able to see about 50%.

- For most patients, the foreign body sensation should go away over time. It is normal if you can still fell the product.
- Continue to rest, do not engage in strenuous activities or operate heavy machinery.
- Avoid rubbing your eyes, strong blinking, or moving PROKERA with your fingers.
- Do not remove your PROKERA device without consulting your eye doctor first.
- Do not swim or soak your face with water.
- Shower only when the eye is tightly closed.
- Use eye drops and other medications as prescribed by your eye doctor.

Your vision may become cloudier and you will be able to see about 20-25%.

• Your vision will become less cloudy and start to improve.

Day 4-5 of PROKERA
Treatment
Continued discharge is common.
Use eye drops and other medicat
Your doctor may schedule you for a

Day 2-3 of

PROKERA

Treatment

• Use eye drops and other medications as prescribed by your eye doctor.

t Your doctor may schedule you for a follow up visit to see how the treatment is going and schedule the removal of the PROKERA device.

Contact your eye doctor right away if you experience increased discomfort, can all of a sudden see clearly or have any other problems with PROKERA.

