# Patients' Guide to Prokera®

What to Expect



"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."

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.

#### 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 process can range from 3-5 days. Depending on the severity of your condition, your doctor may choose to extend the treatment period or place a second Prokera device. Your doctor will schedule a follow-up appointment to check your treatment progress and remove the Prokera lens.

#### **Allergies and Warnings**

If you are allergic to Ciprofloxacin, Amphotericin B, Glycerol, and/or Dulbecco's Modified Eagle Medium (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.

### Day of **Prokera** Insertion

- Have a driver bring you to the appointment.
- Some patients may experience discomfort; this is usually caused by a foreign body sensation but is NOT painful.
- Your doctor may use tape to partially close your eyelid, which can help alleviate the discomfort.
- Prokera is not fully transparent so expect your vision to be somewhat cloudy during treatment.

### 24 Hours after Prokera insertion

- 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, turn red, and exhibit discharge, which is normal and part of the healing process. Notify your doctor if you have any concerns
- 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 to 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 the 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%.

# Day 2-3

after Prokera insertion

- For most patients, the foreign body sensation should go away over time. It is normal if you can still feel 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%.

## Day 4-5

after Prokera insertion

- Your vision will become less cloudy and start to improve.
- · Continued discharge is common.
- Use eye drops and other medications as prescribed by your eye doctor.

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 immediately if you experience increased discomfort, can all of a sudden see clearly or have any other problems with Prokera.

1. McDonald et al. "Treatment Outcomes in the Dry Eye Amniotic Membrane (DREAM) Study." Presented at AAO Annual Meeting 2017, PO055

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



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