

## LACRIFILL<sup>®</sup> Canalicular Gel FAQs

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### In Summary:

- Store at room temperature.
- Ensure the cannula is finger-tight and securely locked to the syringe.
- Apply gentle steady pressure to prime the cannula.
- Clinical discretion can be used for the appropriate cannula size. Dilation may be required with the use of a larger cannula. A 27-gauge Bailey lacrimal cannula was used in the LACRIFILL clinical study.

### **Do I need to treat inflammation of the eye before lacrimal occlusion with LACRIFILL Canalicular Gel?**

No. After administering LACRIFILL<sup>®</sup> Canalicular Gel, the patient's symptoms of dry eye will improve. If necessary, you can treat inflammation after that with anti-inflammatory eye drops. This is actually a better solution, because those drops will remain on the surface of the eye longer after lacrimal occlusion. Otherwise, they tend to drain away from the eye.

That said, if a patient is already routinely using anti-inflammatory eyedrops, they're still a candidate for LACRIFILL Canalicular Gel. In our research, we excluded patients using drops because we wanted to evaluate the effectiveness of LACRIFILL Canalicular Gel without any confounding factors.

### **Is any special preparation needed before instilling LACRIFILL Canalicular Gel?**

The only prep needed is using a drop of the topical anesthetic proparacaine to numb the eye; obviously, patients can experience pain if you accidentally touch the eye. There's no need to clean the eyelids with an antiseptic solution, such as Betadine.

If you suspect a blocked tear duct, you can irrigate it to make sure it's clear before instilling LACRIFILL.

### **Why is there a lower risk of infection with LACRIFILL Canalicular Gel than with traditional plugs?**

Traditional intracanalicular plugs are small pieces of plastic that are placed inside the canaliculus. They are often linked to infections, and even the newer Oasis Form Fit plugs have had some case reports of infections. That's because when you put a plug into the "tube" that is the tear duct, you can have a pool of stagnant tears form above the plug, and this increases the risk of infection.

With LACRIFILL Canalicular Gel, however, you are filling the canalicular opening all the way up to the top with hyaluronic acid gel. The gel completely fills the space; without any pooling of tears, there is no place for the bacteria to grow.

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### **Was tear osmolarity measured in the studies of LACRIFILL Canalicular Gel?**

Even though tear osmolarity is commonly used clinically as an indicator of dry eye, the FDA does not view it as a proven clinical test of dry eye disease. And this measure was only introduced in the last 10 years. Instead, we used tests that have a much longer clinical history: the Schirmer Test, tear breakup time, and corneal staining.

### **Is LACRIFILL Canalicular Gel really still there after 6 months?**

Yes. And we showed that in a few different ways in the research. We did the dye disappearance test, which involves placing a concentrated dye on the surface of the eye, waiting 5 minutes, and then seeing how much of the dye remains. In the study, we saw that the amount of dye remaining at 5 minutes increased immediately after LACRIFILL Canalicular Gel was instilled, and this increase remained the same every time it was tested through 6 months. At that point, we removed LACRIFILL Canalicular Gel as required by the FDA, since it was still considered an investigational device. After that removal, the dye disappearance test started to go back down to where it was before LACRIFILL Canalicular Gel was in there.

In addition, when we performed the irrigation to remove LACRIFILL Canalicular Gel, at first we could feel there was an obstruction. There was initial resistance to irrigation; however, then the obstruction released and we could flush out LACRIFILL.

Finally, the signs and symptoms of dry eye remained improved at 6 months, as measured by the Schirmer's Test, tear breakup time, and corneal staining.

### **Can patients who have LACRIFILL Canalicular Gel treatment still use eye drops?**

Yes. Many of the patients in the study continued to use artificial tears.

### **Moving forward, is there a plan for additional clinical trials?**

We are interested in studying the use of LACRIFILL Canalicular Gel in different populations, such as patients who had cataract surgery or refractive surgery. We know that up to 50 percent will have signs and symptoms of dry eye, and it is very common to use lacrimal occlusion at the time of surgery. One approach might be to randomize to patients to LACRIFILL or no treatment the day before surgery and assess the results.

### **Do prefilled syringes of LACRIFILL Canalicular Gel require refrigeration? How long can they be stored?**

No, the syringes do not require refrigeration

The syringes have a 24-month shelf life from date of manufacture.

### **Is training available, in person or online, to teach me how to administer LACRIFILL Canalicular Gel?**

There are online videos that demonstrate the technique. However, the technique is well known to Eye Care Professionals because it is the same thing you do when you irrigate the tear duct—and this is one of the first procedures you typically learn. It is very simple to instill LACRIFILL Canalicular Gel.

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### **Would any medical conditions contraindicate the use of LACRIFILL Canalicular Gel in a patient?**

Any patient with dry eye signs or symptoms is a candidate. In the clinical trial, we did avoid enrolling people who had a corneal transplant, but they are still candidates for use. The only real contraindication would be if someone already has a blocked tear duct; obviously, there is no role for lacrimal occlusion in a patient with tear duct obstruction.

LACRIFILL should not be administered to patients experiencing epiphora, inflammation of the eye lid, and tearing secondary to dacryocystitis with mucopurulent discharge and any other active ocular or periocular infection, those who are allergic to hyaluronic acid or to the specific device material, and those who have known lacrimal outflow obstruction.

See LACRIFILL IFU for further information.

### **What should patients expect in the first few days after treatment with LACRIFILL Canalicular Gel?**

#### **Are there any symptoms to watch out for that could indicate a problem?**

Patients should expect their eyes to feel better immediately; there are no side effects and no healing process. The tear film will increase right away. In the study, about 8 percent of patients noted that at some point they were having tearing. But no one asked for LACRIFILL Canalicular Gel to be removed due to noticeably watery eyes (or for any reason).

If someone were to have any pain, redness, or inflamed eyelids, they should report those symptoms right away, as they could be signs of infection. But these were not an issue in our research.

#### **Is it generally recommended to fill the upper and lower canaliculus on each eye?**

#### **If I choose to fill two, or only treat one eye, will I have part of a syringe left over?**

There is enough hyaluronic acid gel in the syringe to do all 4 canaliculi. The question is, how severe are the patient's symptoms of dry eye, based on symptoms and anesthetized Schirmer Test? If the result is 0, then it might be recommended to fill all 4 openings. If it's closer to 10, then that would likely not be needed. Also, do patients have signs or symptoms in both eyes? Most people do, since dry eye is a systemic condition and not usually limited to one eye.

Of course, you would only use one syringe per patient, whatever the situation.

#### **Is LACRIFILL Canalicular Gel safe to use in people who have had surgery?**

Yes. A significant percent of patients treated with LACRIFILL Canalicular Gel have had cataract or refractive surgery. It is safe to use in that setting, as mentioned above.

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Rx Only

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