

LIOLI-24 INJECTOR LOADING GUIDE

FOR USE WITH THE EVO VISIAN ICL™ FAMILY OF LENSES



The Lioli Injector System consists of two parts:
Single-use, sterile syringe injector with silicone tip (Figure 1)
Single-use, sterile LubriMATRIX™ treated cartridge (Figure 2)

Part A: Load ICL in Cartridge

1. Open the injector system package and transfer the contents to the sterile field.

CAUTION: Do not handle the cartridge at the tip's opening.

2. Apply a small amount of methylcellulose type viscoelastic in the lens loading chamber and in the cartridge funnel. (Figure 3).

CAUTION: The loading of the ICL is a critical component of the overall procedure and should be performed under an operating microscope. The delivery of the ICL into the posterior chamber is largely dependent on the precise and careful loading of the ICL.

3. Gently remove the ICL from the vial using sterile forceps (Figure 4).

CAUTION: Do not use sharp, rough, or serrated edged forceps; this could damage the ICL.

4. Hold the ICL with forceps and inspect it under the operating microscope to identify and verify the correct orientation of the ICL. It is important that the long jaws of the forceps avoid the optic area of the ICL to avoid damage to this thin and critical area. The footplate marks on the leading right and trailing left haptic indicate that the correct (convex) side of the ICL is facing up. The other center marks are used to guide alignment during loading of the ICL into the Injector cartridge (Figure 4).

5. With the cartridge held in one hand and the forceps holding the ICL in the other, place the ICL in the loading chamber (Figure 5). The cartridge is equipped with grooves under guide rails on opposite ends. This allows rapid and precise loading of the lens.

6. Press the ICL into both guide rails with forceps. This usually requires starting one long edge of the ICL under one rail and rolling the wrist to position the opposite side of the ICL under the other rail. Gently slide the ICL back and forth horizontally to ensure that it moves freely (Figure 6).

CAUTION: The ICL must be convex in the cartridge with both edges below the side rails of the cartridge.

CAUTION: Footplates should not extend/protrude out of the cartridge loading chamber to avoid risk of damaging the lens while closing the cartridge.

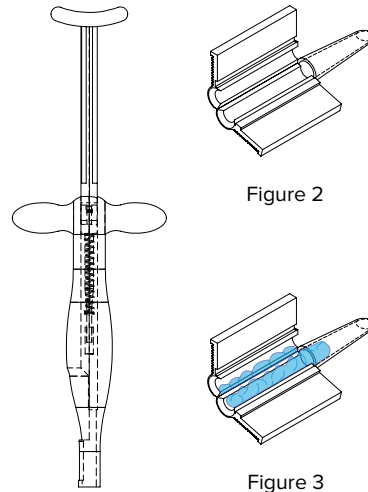


Figure 1

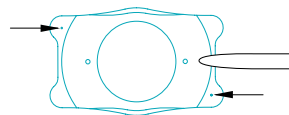


Figure 4

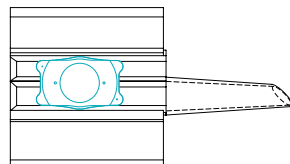


Figure 5

7. Carefully examine the position of the lens to confirm that it is correctly aligned, prior to closing the cartridge (Figure 7).

CAUTION: Watch closely to ensure the ICL does not become trapped at the hinge during the lens loading process.

8. Press the cartridge flaps together until an audible click is heard. This indicates that the cartridge is locked (Figure 8).

Part B: Load Cartridge into Injector and deliver the ICL

9. Retract the silicone-tipped plunger and guide the cartridge into the opening at the front end of the injector (Figure 9) and push the cartridge to the foremost position (Figure 10).

10. Apply a small amount of viscoelastic into the tip of the cartridge funnel.

CAUTION: The ICL should be injected within two minutes after loading. Viscoelastic may lose its lubricity if allowed to stand too long while exposed to air.

11. Carefully press the plunger forward to ensure that the silicone tip correctly enters the loading chamber. Push the lens out of the chamber into the funnel.

Slight resistance when injecting the lens is not indicative of an improperly loaded lens in the cartridge.

CAUTION: Push the plunger until the inner spring begins to compress. Pull the plunger back a few millimeters and then push it forward again. This step ensures that the lens is correctly engaged.

Continue to push the lens until the leading foot plate reaches the tip of the cartridge funnel.

12. Inspect the orientation of the ICL under the operating microscope. The clear funnel of the cartridge enables identification of the center marks on each side of the optic. These marks should be visible at 12 o'clock position and be in straight alignment down the shaft.

13. Insert the cartridge tip through the incision and into the anterior chamber. Press the plunger forward slowly in order to push the lens forward.

14. Slowly inject the ICL and withdraw the cartridge from the eye.

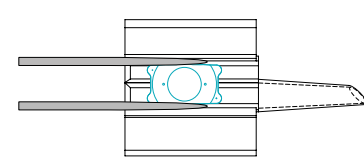


Figure 6

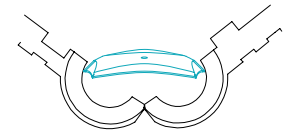


Figure 7

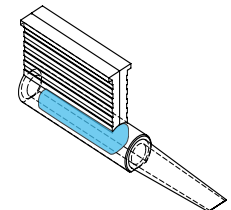


Figure 8

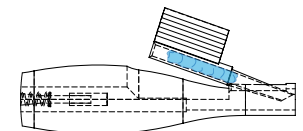


Figure 9

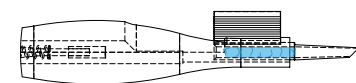


Figure 10