

The Lioli Injector System consists of two parts:

Single-use, sterile syringe injector with silicone tip (Figure 1)

Single-use, sterile LubriMATRIX™ coated cartridge (Figure 2)

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

3. Gently remove the IOL from the vial using sterile forceps. Retrieve the IOL from its packaging and grasp the full length down the long axis. (Figure 4)

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

4. With the cartridge held in one hand and the forceps holding the IOL in the other, place the IOL 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.

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

CAUTION: The IOL haptics should not extend/protrude out of the cartridge loading chamber to avoid risk of damaging the haptic while closing the cartridge.

Figure 1

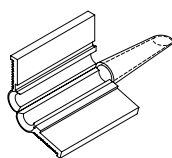
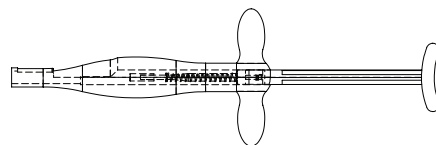


Figure 2

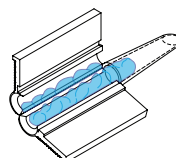


Figure 3

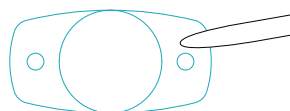


Figure 4

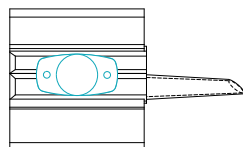


Figure 5

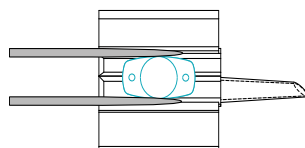


Figure 6

**Please see reverse side for additional instructions.*

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

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

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

4. Hold the Visian ICL with forceps and inspect it under the operating microscope to identify and verify the correct orientation of the Visian ICL. It is important that the long jaws of the forceps avoid the optic area of the Visian 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 Visian ICL is facing up. The other center marks are used to guide alignment during loading of the Visian ICL into the Injector cartridge (Figure 4).

5. With the cartridge held in one hand and the forceps holding the Visian ICL in the other, place the Visian 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 Visian ICL into both guide rails with forceps. This usually requires starting one long edge of the Visian ICL under one rail and rolling the wrist to position the opposite side of the Visian ICL under the other rail. Gently slide the Visian ICL back and forth horizontally to ensure that it moves freely (Figure 6).

CAUTION: The Visian 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

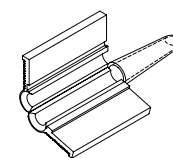
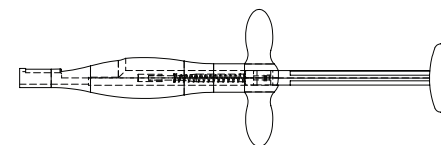


Figure 2

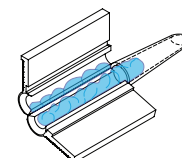


Figure 3

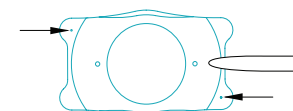


Figure 4

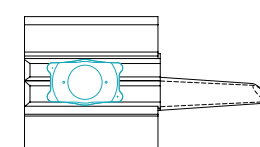


Figure 5

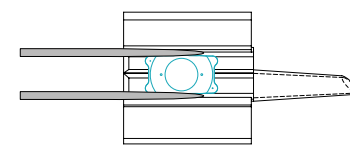


Figure 6

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6. 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 IOL does not become trapped at the hinge during the lens loading process.

7. 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 nanoFLEX IOL

8. 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).

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

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

10. 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 haptic reaches the tip of the cartridge funnel.

11. Inspect the alignment of the IOL under the operating microscope. The clear funnel of the cartridge enables confirmation of the axial alignment and symmetry of the IOL in the cartridge.

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

13. Slowly inject the IOL and withdraw the cartridge from the eye.

Figure 7

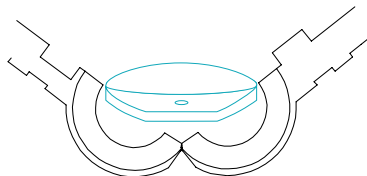


Figure 8

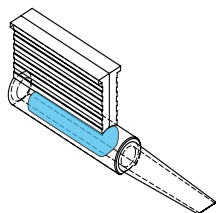


Figure 9

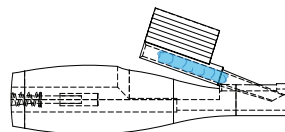
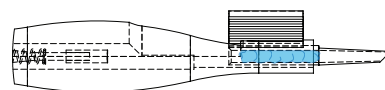


Figure 10



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 Visian 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 Visian 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 Visian 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 Visian 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 Visian ICL and withdraw the cartridge from the eye.

Figure 7

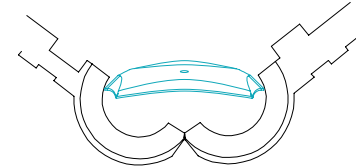


Figure 8

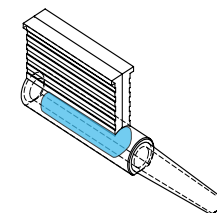


Figure 9

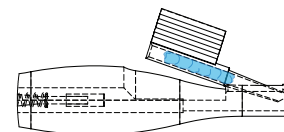


Figure 10

