

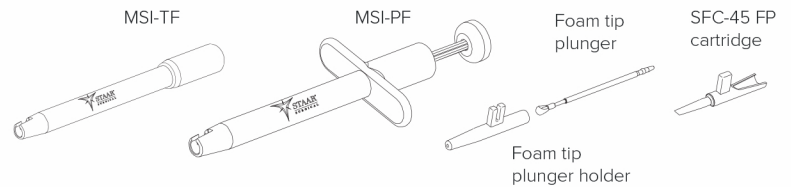
MSI-TF, MSI-PF INJECTOR LOADING GUIDE

Use with the Visian ICL



The STAAR Injector delivery system consists of four parts:

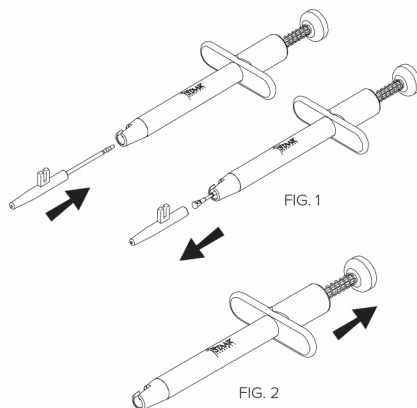
1. The sterile reusable Injector Threaded MSI-TF, or Plunger MSI-PF.
2. Sterile, single-use, disposable SFC-45 Cartridge (do not resterilize).
3. Sterile, single-use, disposable Foam Tip Plunger (do not resterilize).
4. Sterile, single-use, disposable Foam Tip Plunger holder (do not resterilize).



Prepare the FTP and the Injector

Step 1.

1. Open the pouch for the Injector, the outer pouch for the FTP, and the pouch for the Cartridge and transfer contents to the sterile field.
2. Open the inner pouch and remove the FTP and holder. The base of the FTP protrudes out the back of the holder.
3. Insert the FTP into the Injector, base first, (the vertical tab of holder is not intended to be snap locked into notch of Injector). While holding the tab in place, advance the Injector cap until the ball end of the FTP interlocks with the Injector. A click can be felt and heard when the plunger is properly secured.
4. Retract the Injector plunger fully. The FTP will remain locked in place.
5. Remove the holder by sliding it back out of the front of the Injector. (Fig. 1 & 2)



6. Place the assembled FTP and Injector into BSS such that the tip of the Injector is submerged up to the FTP. (Fig. 3)



FIG. 3

Caution: Hydration of the foam tip is extremely important as insufficient hydration may cause trapping of the ICL between the plunger and cartridge upon ICL delivery.

Load ICL in Cartridge

Step 2.

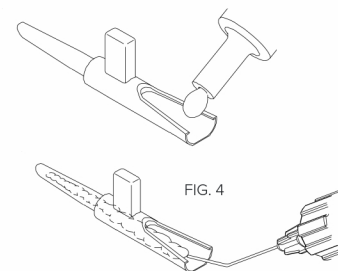
CAUTION: Load the Visian ICL immediately prior to injection. ICL should not be left folded in Cartridge for more than 1-2 minutes.

1. Open the pouch for the Cartridge package, and transfer the tray to sterile field. When ready to use, open tray and remove the Cartridge.

CAUTION: Do not handle the cartridge from the tip

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

2. Fill the Cartridge first with BSS followed by a partial fill with approximately 0.3mL methylcellulose type viscoelastic material, creating a trail out the back of the loading area. (Fig. 4)



3. Gently remove the ICL from the vial with forceps. (Fig. 5)

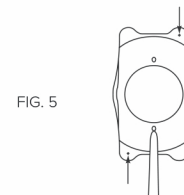


FIG. 5

CAUTION: Do not use sharp or rough edge forceps; this could damage the Visian ICL. The ICL must remain hydrated.

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 span 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.

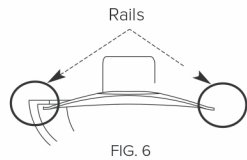
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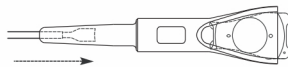


5. With the Cartridge held in one hand and the forceps holding the ICL in the other, the ICL is placed in the Cartridge bay. Place the ICL into the Cartridge bay so that the long axis of the ICL is positioned into the groove, under each side-rail of the Cartridge. This usually requires starting one long edge of the ICL under one rail and rolling the wrist to position the opposite side of the ICL under the opposing rail

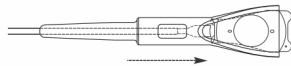
Note: The ICL must be convex in the Cartridge with both edges below the side rails of the Cartridge. (Fig. 6)



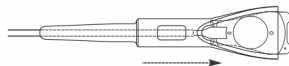
6. Close the jaws of the Visian ICL loading forceps and insert them into the barrel, from the front of the cartridge. (Fig. 7)



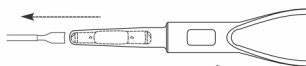
7. Advance the forceps through cartridge until the forcep jaws are about to contact the leading edge of the ICL. (Fig. 8)



8. Open the jaws of the forceps and grasp the footplate of the ICL, so that the ICL positioning mark is aligned with the jaws. (Fig. 9)



9. Slowly pull the ICL into the barrel while moving the cartridge in the opposite direction. Observe the ICL positioning marks on either side of the optic to confirm alignment as you advance the ICL. Continue this process until the ICL is positioned within the cartridge so that its leading edge is adjacent to the end of the cartridge. Release the ICL and remove the forceps. (Fig. 10)



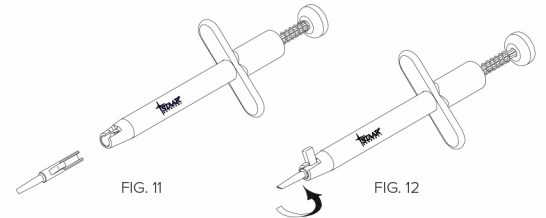
10. Any air bubbles should be evacuated from the loaded Cartridge with methylcellulose type viscoelastic injected into the tip of the Cartridge using the cannula to backfill the Cartridge.

Step 3.

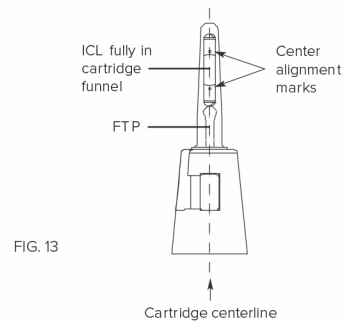
Load Cartridge into Injector and delivery of ICL

CAUTION: The Visian ICL should be injected within 1-2 minutes after loading. Viscoelastic materials tend to lose their lubricity if exposed too long to air.

1. Slide Cartridge into the front of the Injector and snap lock the vertical tab into position. (Fig. 11 & 12)



2. Advance the plunger until it is in contact with the ICL. The final ICL position should be within approximately 2mm of the end of the cartridge.
3. Inspect the orientation 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 the 12 o'clock position and be in straight alignment down the shaft. (If the ICL is not aligned or properly oriented, the ICL may be twisted and should be injected into the Cartridge tray and the loading process repeated). (Fig. 13)



4. The fully assembled injector is placed tip down into a container of BSS to maintain lens hydration. (Fig. 14)

CAUTION: The maximum recommended time for the loaded ICL to remain in the Injector prior to surgery is 1-2 minutes.

