HOW SUPPLIED

Each iStent inject W System is supplied with a sterile injector, a single-use injector, a single-use retractor, an inserter, and a single-use inserter. The single-use inserter is preassembled onto the single-use injector. The blister tray includes two intraocular stents (only the inner contents of the blister tray are sterile). Two stents (the iStent inject W System is sterilized by gamma irradiation). The expiration date of the device package (tray lid) is the sterility expiration date, and the expiration date is clearly indicated on the outside of the tray lid. Sterility is assured if the tray seal is not broken until the expiration date. This device should not be used past the individual expiration date.

INSTRUCTIONS FOR USE

6. Open the jaws by pressing the trigger (front) button to draw back the insertion tube and trocar.

7. Locate the slot in the insertion tube and verify the stent is securely in place.

8. While looking through the eye, relocate the tip of the injector for implantation of the second stent; repeat steps 6 through 7.

9. Remove the injector from the eye.

10. Irrigate the anterior chamber with balanced salt solution (BSS) through the corneal wound to remove all viscoelastic. Press down on the posterior edge of the incision as needed to facilitate complete removal of viscoelastic.

11. Insert the saline with solution as needed to achieve normal physiologic pressure.

12. Ensure the corneal incision is sealed.

Retrieval of an Implanted Stent

1. Prepare the patient as one would for implantation surgery.

2. Open the eye at the preferred location in order to reach the stent's location. Use a clear corneal incision measuring approximately 1.5mm in length.

3. Use viscoelastic to isolate the anterior chamber to create access to the stent. Then, move the stent away from a delicate structure if loose, and/or protect intraocular tissues.

4. Use a gonioscope if needed to visualize the location of the stent in the trabecular meshwork.

5. Insert a micro forceps device through the corneal wound.

6. Open the eye at the preferred location, move the trigger button and grasp the stent. The device should be immersed in any convenient and secure location.

7. Remove the stent in the jaws of the micro forceps device from the eye taking care not to contact the iris, cornea, or lens, if possible.

8. Irrigate the anterior chamber with balanced salt solution (BSS) through the corneal wound to remove all viscoelastic.

9. Remove the inserter, as this may cause elevated episcleral venous pressure.

10. Ensure that the corneal incision is sealed.

11. Ensure that the corneal incision is sealed.

WARNINGS/PRECAUTIONS

• For prescription use only.

• This device has not been studied in patients with uveitic glaucoma.

• The surgeon should assess that placement of the stents, without concomitant cataract surgery in patients with uveitic glaucoma, may facilitate the formation or progression of cataract.

• Do not use the device if the Tyvec® lid has been opened or the packaging appears damaged. In such cases, the sterility of the device may be compromised.

• Due to the sharpness of certain stent components, care should be exercised to grasp the inserter, as this may result in infection and/or permanent damage to the delicate structure if loose, and/or protect intraocular tissues.

• Observation of surgical cases is demonstrated.
Potential complications

Intraoperative or postoperative adverse events may be device-related or non-device related.

Potential intraoperative events are as follows:
- Cataract formation and/or progression in phakic patients may occur.
- Compromise of trabecular meshwork.
- Glaucoma surgery (trabeculectomy).
- Trabeculectomy.
- IOL dislocation (in pseudophakic eyes).
- IOP increase requiring management with oral or intravenous medications or with surgical intervention.
- Pupil block.
- Retinal complications (dialysis, flap tears, detachment, or proliferative vitreoretinopathy).
- Secondary surgical intervention including, but not limited to, the following:
  - Trabeculectomy
  - IOL repositioning or removal
  - Cataract repositioning or removal
  - Significant corneal complications including edema, opacification, descemetocele, and perforation
  - Significant damage to the trabecular meshwork
  - Significant iris damage
  - Significant loss of best corrected visual acuity (BCVA)
  - Stent dislocation or malposition
  - Stent obstruction

Storage requirements

The device should be stored at room temperature (15-30°C).