Carefully examine the package containing the PRESERFLO™ MicroShunt for signs of damage that could compromise sterility. If damaged, discard the device.

The PRESERFLO™ MicroShunt is designed to drain posteriorly. Implantation is at the surgeon’s discretion, either in the superonasal or superotemporal quadrant of the eye, avoiding the rectus muscles.

**BEFORE SURGERY**

Kit Materials

- 3 mm scleral marker
- Violet pen
- Three LASIK shield sponges
- 1 mm slit angled knife
- 25G needle
- PRESERFLO™ MicroShunt

Surgical instruments required:

- Conjunctival forceps
- Toothed and smooth forceps
- Blunt dissection scissors
- Spring/conjunctival scissors
- Spears
- 23G TW cannula
- Bipolar diathermy
- Balanced salt solution
- Suture material
- Mitomycin C
- Syringes
- Anesthesia

Anesthetize and Prepare the Eye

1. Ensure the patient’s eye is turned down as far as possible so that the operative site is parallel to the floor.
2. Anesthetize the eye at the surgeon’s discretion.
3. Remove the PRESERFLO™ MicroShunt from sterile packaging onto the sterile field.
4. Wet the PRESERFLO™ MicroShunt using a solution of Balanced Salt Solution (BSS).

Corneal Traction and Conjunctival Flap

1. At the surgeon’s discretion, perform corneal traction with 7-0 Vicryl® suture.
2. Make a 6-8 mm radial limbal peritomy incision to ensure good posterior view.
3. Using blunt scissors, separate the conjunctiva and Tenon’s from the limbus, creating a pocket over a circumference of 90°-120° from the corneal apex (10:30 to 1:30), that is at least 8-10 mm deep.
3 Cauterization and Application of Mitomycin C (MMC)

- Use cauterization or bipolar diathermy to achieve a dry pocket. Avoid excessive cautery, which could increase the risk of scarring.
- Apply 3 LASIK sponges saturated with 0.2-0.4 mg/ml of MMC in the conjunctiva and Tenon’s pocket for 2-3 minutes, avoiding contact with the conjunctival wound edge.
- Remove and irrigate the operative area using the syringe prepared with BSS.
- Ensure there is no active bleeding of the planned PRESERFLO™ MicroShunt entry.

4 Preparation of Anterior Chamber Entrance Site

- Ink the 3 mm scleral marker with the violet pen and mark 3 mm from the limbus (blue-grey zone) to ensure corneal entry is parallel to the iris and away from the corneal endothelium.

5 Using the MANI Slit Angled 1.0 Knife

- At the mark point, use the MANI slit angled 1.0 mm knife at a 20 degree angle to create a shallow scleral pocket that is 2 mm long, stopping at the limbus prior to entering the AC.

6 Creating a Scleral Tunnel

- Bend 3 mm of the 25G needle to achieve a 120 degree angle.
- Using traction suture, bring the eye down (towards feet) while entering scleral tunnel. Retrace the scleral pocket by entering at a 20 degree angle and move the 25G needle left and right upon entering the incision to avoid a false passage. Bring the eye slowly to the neutral position while approaching the limbus.
- Once the apex of the scleral pocket has been reached, angle the needle a further 20 degrees while slowly bringing the eye back up towards primary position and then enter the eye to be at the iris plane.

7 Insertion of PRESERFLO™ MicroShunt into Anterior Chamber

- At the scleral tunnel, position the PRESERFLO™ MicroShunt tube bevel up. Ensure the fin face is parallel to the scleral surface.
- Using smooth tip forceps gently insert the PRESERFLO™ MicroShunt 1 mm at a time into the AC until at least 2/3 of the fin is tucked under the scleral flap.
- Use of excessive force will result in temporary bending of the PRESERFLO™ MicroShunt and increase the difficulty of entry.
- If not properly formed or if implant is not properly positioned, another tract can be made approximately 1 mm to either side of the original tract. If the PRESERFLO™ MicroShunt is damaged during the procedure, use a new PRESERFLO™ MicroShunt and use a new tract.
8 Verify Position of the Implant in AC and Confirmation of Aqueous Flow

After successful insertion of the PRESERFLO™ MicroShunt, check that the tube position in the AC is not in contact with the cornea or iris and that there is flow of aqueous. If flow is not visible, consider one or more of the following actions: applying gentle pressure on the eye (sclera, limbus, cornea), filling the AC with BSS through a paracentesis, or using a 23G thin wall 8 mm bent canula to inject BSS into the distal end of the PRESERFLO™ MicroShunt to prime the tube.

Once flow has been confirmed, tuck the end of the PRESERFLO™ MicroShunt tube under the conjunctival Tenon’s flap on the scleral surface making sure it is not caught in Tenon’s capsule. Ensure all Tenon’s cover the MicroShunt to prevent a scar tissue obstruction. Tenon’s management is key.

It is recommended that intraoperative gonioscopy be performed to assess the position of the proximal tip of the PRESERFLO™ MicroShunt in the AC to ensure that there is sufficient clearance from the cornea and iris.

9 Tenon’s and Conjunctival Closure

Using sutures at the surgeon’s discretion (i.e., nylon, vicryl), reposition the Tenon’s capsule 1 mm back to the limbus and suture, ensuring Tenon’s are covering the PRESERFLO™ MicroShunt without obstruction. Reposition the conjunctiva to the limbus and suture.

Use a moistened fluorescein strip to check for a conjunctival leak. Leaks may be closed with additional sutures. Verify the presence of the proximal end of the PRESERFLO™ MicroShunt in the AC. Remove corneal traction suture if it was used.

Apply antibiotic and steroidal medication postoperatively as appropriate.

Images courtesy of Professor Ingeborg Stalmans from University Hospitals Leuven. All steps derived from PRESERFLO™ MicroShunt Instructions for Use.
The use of PRESERFLO™ MicroShunt requires a prior specific treatment by administrating an antifibrotic agent called Mitomycin C (MMC), according to the state of the art surgical treatment of glaucoma. The PRESERFLO™ MicroShunt Instructions for Use provide detailed information on the use of Mitomycin C (MMC), which was used in studies at a dose of 0.2–0.4 mg/ml and with a duration of 2–3 minutes.

PRESERFLO™ MicroShunt is indicated for patients with primary open-angle glaucoma where IOP is inadequately controlled by maximally tolerated medical therapy. For important safety information, please consult the PRESERFLO™ MicroShunt Instructions for Use.

**PROCEDURE STEPS**

1. Apply anaesthetic beneath the conjunctiva (injected either locally or as a peribulbar block, or applied topically).
2. Make a 6-8 mm radial limbal peritomy incision and under Tenon's capsule.
3. Using blunt scissors, separate the conjunctiva and Tenon's from the limbus, creating a pocket over a circumference of 90°–120° from the corneal apex (10:30 to 1:30), and at least 8-10 mm deep.
4. Mark 3 mm from the limbus (blue-grey zone) to ensure corneal entry is parallel to the iris and away from the corneal endothelium.
5. Bend 3 mm of the 25G needle to achieve a 120 degree angle. Once the apex of the scleral pocket has been reached, angle the needle another 20 degrees while slowly bringing the eye back up towards primary position and then enter the eye to be at the iris plane.
6. Mark 3 mm from the limbus (blue-grey zone) to ensure corneal entry is parallel to the iris and away from the corneal endothelium.
7. Use cauterization to achieve a dry pocket. Apply 3 LASIK sponges saturated with 0.2–0.4 mg/ml of MMC* in the conjunctiva and Tenon's pocket for 2-3 minutes, avoiding contact with the conjunctival wound edge, followed by irrigation with BSS.
8. Position the PRESERFLO MicroShunt tube bevel up. Ensure the fin face is parallel to the scleral surface. Using smooth tip forceps, gently insert the PRESERFLO™ MicroShunt 1 mm at a time in the AC until at least 2/3 of the fin is tucked under the scleral flap.
9. Using sutures at the surgeon’s discretion (i.e., nylon, vicryl), reposition the Tenon’s capsule 1 mm back to the limbus and suture, ensuring Tenon’s are covering the MicroShunt without obstruction. Reposition the conjunctiva to the limbus and suture. Check for leaks.

---

* The use of PRESERFLO MicroShunt requires a prior specific treatment by administrating an antifibrotic agent called Mitomycin C (MMC), according to the state of the art surgical treatment of glaucoma. The PRESERFLO MicroShunt Instructions for Use provide detailed information on the use of Mitomycin C (MMC), which was used in studies at a dose of 0.2–0.4 mg/ml and with a duration of 2-3 minutes.

PRESERFLO MicroShunt is indicated for patients with primary open-angle glaucoma where IOP is inadequately controlled by maximally tolerated medical therapy. For important safety information, please consult the PRESERFLO MicroShunt Instructions for Use.