

OMNI

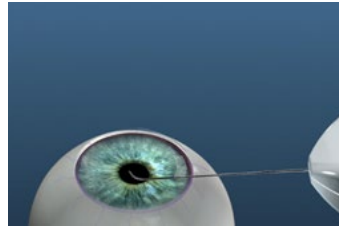
OMNI® SURGICAL SYSTEM

# Priming and Procedure Guide

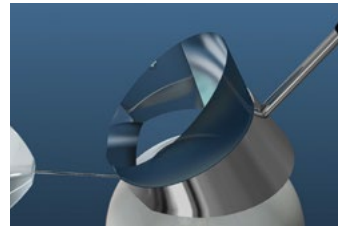


# Canaloplasty Procedure

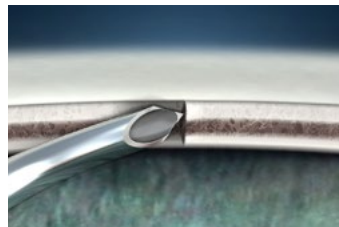
## Gain Access



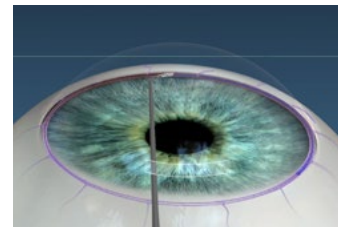
**01**  
Through a clear corneal incision, advance cannula across the anterior chamber towards the nasal iridocorneal angle.



**02**  
Apply the gonioprism.

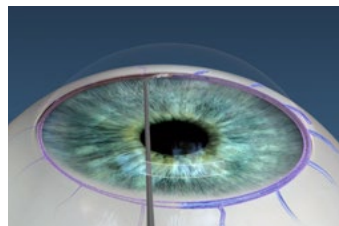


**03**  
Use cannula tip to gain access into canal.

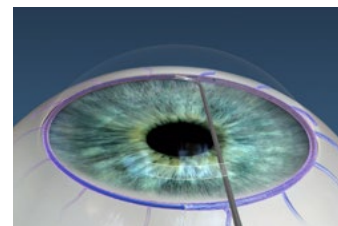


**04**  
Gently advance microcatheter into and around the canal.

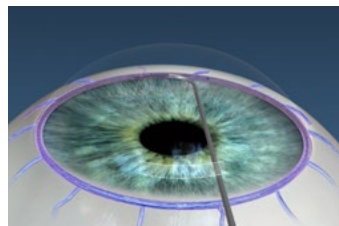
## Deliver Viscoelastic Fluid



**05**  
Upon retraction of the microcatheter into the cannula, a controlled volume of viscoelastic fluid is delivered.



**06**  
To repeat the process in the opposite hemisphere, the cannula should be withdrawn from the anterior chamber and oriented in the opposite direction.



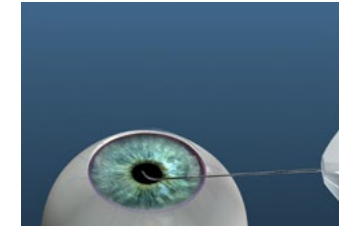
**07**  
A 360° canaloplasty is completed.



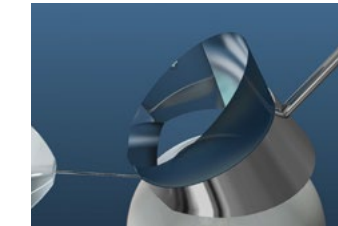
Scan to watch procedure animation

# Trabeculotomy Procedure

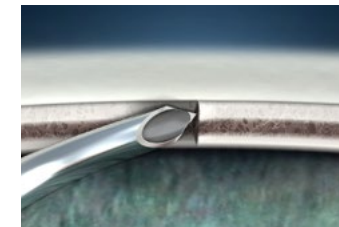
## Gain Access



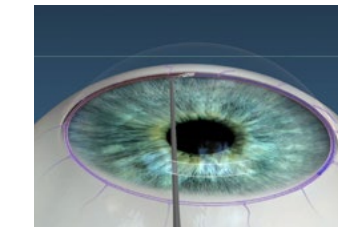
**01**  
Through a clear corneal incision, advance cannula across the anterior chamber towards the nasal iridocorneal angle.



**02**  
Apply the gonioprism.

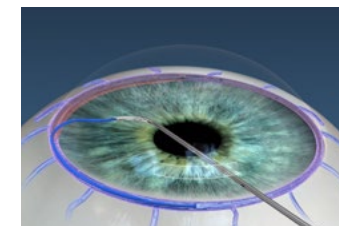


**03**  
Use cannula tip to gain access into canal.

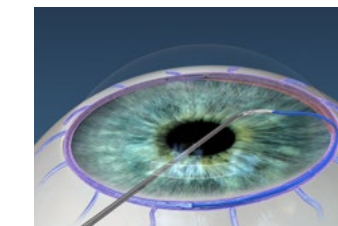


**04**  
Gently advance microcatheter into and around the canal.

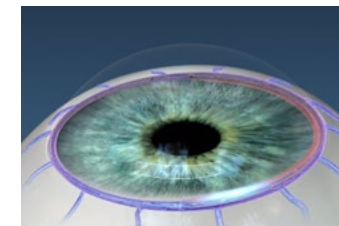
## Perform Trabeculotomy



**05**  
Withdraw microcatheter from the eye to unroof Schlemm's canal and create up to 180° trabeculotomy.

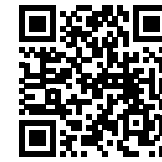


**06**  
To repeat the process in the opposite hemisphere for a trabeculotomy of the remaining 180° of meshwork, the cannula should be withdrawn from the anterior chamber and oriented in the opposite direction.



**07**  
A 360° trabeculotomy is completed.

# Priming Guide



Scan to watch priming video

## Prep the Device

01

### Unbox Your Device

Remove the OMNI® Surgical System from carton. Identify and locate the arrow in the upper left-hand corner. Pull and peel Tyvek sterile barrier and remove the OMNI device from the packaging tray with sterile gloves by the soft grip sides.

02

### Handle With Care

Avoid touching or damaging the cannula tip. Inspect the device closely to make sure it isn't damaged. Remove cannula side first from tray, followed by handle.

03

### Flush the Viscoelastic Cartridge

While holding upright, fully flush the viscoelastic cartridge with COHESIVE viscoelastic fluid prior to attaching it to the Luer fitting.

03



## Prime the Device

04

### Attach the Viscoelastic Cartridge

Directly attach the cartridge to the Luer fitting. Make sure to only rotate the OVD cartridge clockwise, in order to avoid inadvertent removal of the luer fitting. Hold the OMNI device, now connected to a viscoelastic cartridge, UPRIGHT before proceeding. Do not use any separate nozzles or needles, as these may damage the OMNI device.

05

### Prime the Device

While holding the combined OMNI and viscoelastic cartridge pointing UPWARD, SLOWLY (approximately 10 seconds) inject viscoelastic into the proximal end of the OMNI device until viscoelastic flow is visualized coming from the cannula tip. Once viscoelastic is seen flowing out of the cannula tip, the device is fully primed with viscoelastic and air should now be fully flushed from the device. Stabilize device, luer and viscoelastic cartridge so no rotation occurs during priming.

06

### Remove the Viscoelastic Cartridge

Once the device is primed, remove the viscoelastic cartridge and removable luer from the device.

06



07

### Use the Device

The device is ready to use after completing the first six steps.

## Dispose of Device

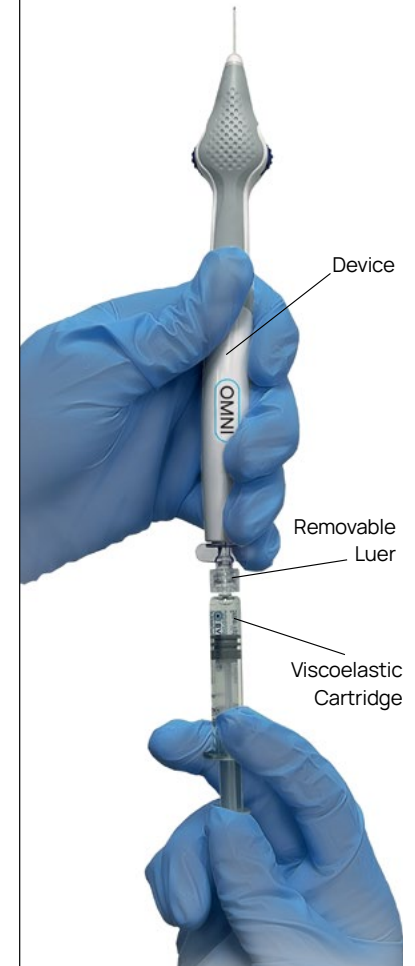
08

### Dispose of Device

Follow your facility's procedures for sharps and biohazardous waste disposal. If a complication occurs, retain the device so it can be returned for analysis.

**Note:** A typical cohesive OVD comes in a 0.45mL cartridge, this is the same as 450µL. OMNI needs only 11µL.

**Important Reminder:** The surgeon should avoid contacting the wheel from below with fingers or gloves as this will prevent the rotation of the wheel, and the catheter will not advance.



**INDICATIONS FOR USE:** The OMNI® Surgical System is indicated for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary openangle glaucoma.

**Contraindications:** Do not use the OMNI in any situations where the iridocorneal angle is compromised or has been damaged (e.g., from trauma or surgery), since it may not be possible to visualize the angle or to properly pass the microcatheter. Do not use the OMNI in patients with angle recession; neovascular glaucoma; chronic angle closure; narrow-angle glaucoma; traumatic or malignant glaucoma; or narrow inlet canals with plateau iris. Do not use the OMNI Surgical System in quadrants with previous MIGS implants.

Please refer to the full Instructions For Use, available at [omnisurgical.com](http://omnisurgical.com), for warnings, precautions, and adverse event information.

