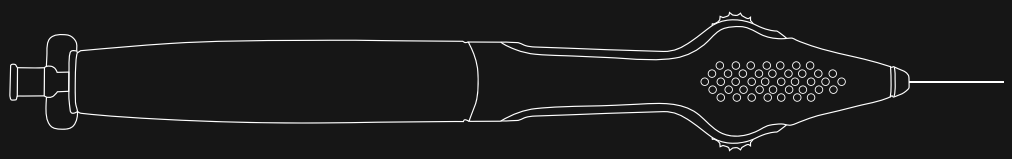
OMNI Edge

OMNI® EDGE SURGICAL SYSTEM

Instructions for Use



Sight Sciences®

OMNI Edge

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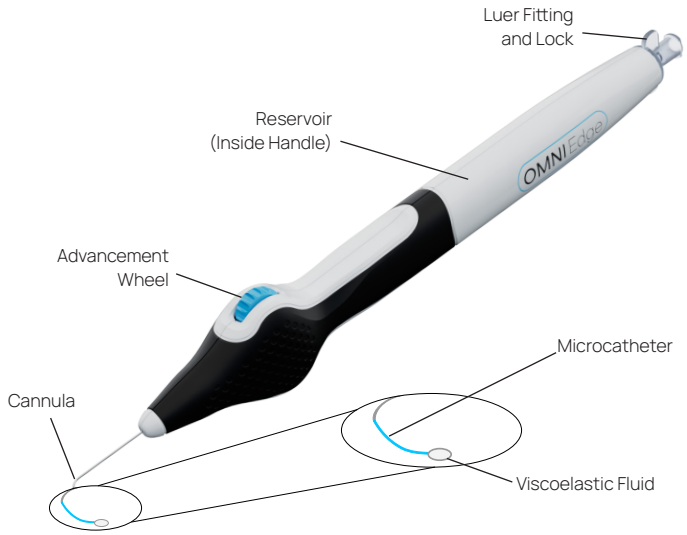
Device Description

The OMNI® Edge Surgical System (OMNI Edge), a member of the OMNI® Surgical System product family, is a single-handed, manually operated device designed to provide controlled delivery of viscoelastic fluid into Schlemm's canal and to cut trabecular meshwork tissue using a microcatheter. The sterile device integrates an access cannula, a microcatheter, an internal fluid reservoir, and a catheter advancement and retraction wheel mechanism all into a single disposable device.

Using only a single clear corneal incision to access the trabeculocanalicular aqueous outflow system, OMNI Edge facilitates the transluminal viscodilation of all 360 degrees of Schlemm's canal and the cutting of up to 360 degrees of trabecular meshwork from an ab interno approach. The system can be used with commercially available viscoelastics, such as Healon® PRO or Healon GV® PRO from Johnson & Johnson Vision, Amvisc® from Bausch & Lomb, or PROVISC® from Alcon.

INDICATIONS FOR USE

The OMNI® Edge 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 open-angle glaucoma.



CONTRAINDICATIONS

1. Do not use the OMNI Edge 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.
2. Do not use the OMNI Edge in patients with angle recession; neovascular glaucoma; chronic angle closure; narrow-angle glaucoma; traumatic or malignant glaucoma; or narrow inlet canals with plateau iris.
3. Do not use the OMNI Edge in quadrants with previous MIGS implants.

WARNINGS

1. Do not use in cases where there is insufficient visibility to properly see the iridocorneal angle. The following conditions may prohibit sufficient visualization required for safe and successful cannula and microcatheter placement: corneal edema, corneal haze, corneal opacity, or any other conditions that may inhibit gonioscopic view of the iridocorneal angle and intended cannula entry location.
2. Perform gonioscopy prior to taking a patient to surgery to exclude congenital anomalies of the iridocorneal angle, anterior segment dysgeneses, peripheral anterior synechiae (PAS), rubeosis, and any other angle abnormalities that could lead to improper placement of the cannula and microcatheter and pose a hazard.
3. Maintain direct microscopic or gonioscopic visualization of the cannula tip and microcatheter tip at all times during the procedure to facilitate advancement and to avoid inadvertently damaging intraocular structures, kinking the microcatheter or unintended tearing of trabecular meshwork.
4. The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. If intraocular pressure is not adequately maintained after surgery, the surgeon should initiate appropriate management of intraocular pressure.

PRECAUTIONS

1. The OMNI Edge is indicated only for use with cohesive viscoelastic fluid. Do not use with dispersive viscoelastic fluid or viscoadaptive fluids.
2. Observe all usual precautions undertaken during intraocular surgery.
3. Use aseptic technique and ensure OMNI Edge and field sterility as is customary during intraocular surgery.
4. This product is sold in a STERILE condition and is intended for a single use. Do not reuse or re-sterilize the product. Device reuse may lead to issues with product function and/or could lead to infection and patient injury.
5. Handle the OMNI Edge cannula carefully to avoid kinking or damaging the cannula or microcatheter.

6. The OMNI Edge involves the use of a sharp tipped cannula. Handle with care. Avoid touching the cannula tip to any unintended surfaces as this may damage or compromise cleanliness of the tip.
7. Do not use the cannula tip to make an incision in the eye to access the anterior segment.
8. Mixing of quaternary ammonium salts, such as benzalkonium chloride, with sodium hyaluronate (viscoelastic fluid) results in the formation of a precipitate. Use of fluids containing such salts during ocular irrigation must be avoided if using the OMNI Edge device loaded with sodium hyaluronate (viscoelastic fluid).
9. There is a possibility for early, short-term intraocular pressure rise when using certain viscoelastic fluids to maintain the anterior chamber. The anterior chamber should be irrigated free of such viscoelastics at the conclusion of surgery to reduce the likelihood of an acute rise in intraocular pressure.
10. The safety and effectiveness of the OMNI Edge was not studied in phakic subjects; the incidence of cataract formation or progression is unknown.
11. The evaluation of device effectiveness in subjects with baseline IOP ≤18 mmHg was significantly limited by the confounding effect of cataract surgery, lack of medication washout, retrospective design, and small sample size.
12. Contents are sterile when the package is sealed and undamaged. Do not use if the product or seal appears damaged or is past its expiration date.

Federal (USA) law restricts this device to sale, distribution, or use by or on the order of a physician. Physician training (reading these Instructions for Use) is required prior to use of the OMNI Edge Surgical System.

Clinical Study Summary

A multi-center retrospective study using the OMNI Surgical System, titled *"A Retrospective, Observational, Multicenter, 12-Month Follow-Up Study of Patients with Open-Angle Glaucoma Treated with the OMNI Surgical System as a Standalone Procedure in Pseudophakic Patients or Combined with Cataract Surgery (ROMEO)"* has evaluated the safety and efficacy of canaloplasty (viscodilation of Schlemm's canal) followed by trabeculotomy through 12-month follow-up.

STUDY DESIGN

"ROMEO" was a retrospective, observational, multicenter, consecutive study of all eyes meeting eligibility criteria treated with the OMNI Surgical System from eleven multi-subspecialty ophthalmic practices in eight states (AL, AR, CA, KS, LA, MO, NY, TX) in the United States. All surgeries took place between March 14, 2018 and June 20, 2019. This study was not randomized or masked. To mitigate the risk of selection bias, enrollment was consecutive/sequential based on the date of OMNI surgery and included all eligible patients up to the enrollment limit at each investigative site. No site enrolled > 25% of study patients.

The retrospective nature of the study ensured that all IOP measurements and physician decisions regarding medication had already been made and recorded in the medical record outside of the context of the study. This study evaluated cases where surgeons used the OMNI Surgical System for ab-interno canaloplasty (viscodilation of Schlemm's canal) and trabeculotomy as a standalone procedure or in combination with cataract extraction. Each site had collected data on IOP, the use of ocular hypotensive medications and safety in patients with open angle glaucoma (OAG). The study was conducted in accordance with the principles set forth in the Declaration of Helsinki and under Institutional Review Board oversight.

All patients had undergone a complete ophthalmic examination including slit-lamp and dilated fundus examinations, best corrected visual acuity (BCVA), Goldmann applanation tonometry, gonioscopy, and automated perimetry prior to surgery. For most patients this preoperative exam was within 60 days of surgery (mean 31.2 days, median 24 days, 90th percentile 63 days). The IOP measured at this exam was used as the baseline IOP.

Postoperative follow-up examinations were performed at 1, 6, and 12 months. Follow-up examinations included IOP measurement, BCVA, slit lamp examination, ophthalmic medication reporting, and adverse event reporting.

Description of Study Patients

Inclusion criteria included 45 years of age or older, underwent transluminal viscoelastic delivery and trabeculotomy using the OMNI Surgical System with at least 273 to 456 days of follow-up, either had a cataract that was decided to be removed or were pseudophakic at the preoperative visit, diagnosed with open-angle glaucoma including pigmentary (PG) and pseudoexfoliative glaucoma (PXG), visual field mean deviation not worse than -12 dB, on 0-4 topical ocular hypotensive agents, and had open angles (Shaffer grade ≥ 3). Eyes were excluded for prior filtration surgery at any time prior to the study period, laser trabeculoplasty, cycloablative, or MIGS implant surgery procedures within 6 weeks of the OMNI procedure, any concurrent IOP-lowering procedure, preoperative medicated IOP > 36 mmHg, cup to disc ratio > 0.9, or forms of glaucoma other than OAG.

Demographics

A summary of the patient demographics is presented in Table 1.

TABLE 1. Demographic and clinical features. All Patients

Variable	All (N= 129)	IOP ≤ 18 mmHg (N= 81)	IOP > 18 mmHg (N= 48)	+Cataract (N= 81)	Standalone (N= 48)
Gender (n, %)					
Male	61 (47)	37 (46)	24 (50)	39 (48)	22 (46)
Female	68 (53)	44 (54)	24 (50)	42 (52)	26 (54)
Mean Age (SD, Min, Max)	72.1 (8.6, 51, 94)	71.9 (8.6, 51, 94)	72.4 (8.5, 56, 88)	70.3 (8.0, 51, 89)	75.0 (8.7, 56, 94)
Diagnosis (n, %)					
POAG	122 (94.5)	77 (95)	45 (94)	76 (94)	46 (96)
PXF	6 (4.7)	4 (5)	2 (4)	5 (6)	1 (2)
PG	1 (0.8)	-	1 (2)	-	1 (2)
Mean Deviation, dB (SD, Min, Max)	-5.1 (3.8, -14.4, 9.4)	-5.1 (3.6, -13.4, 9.4)	-4.9 (4.0, -14.4, 0.9)	-4.8 (3.7, -14.4, 9.4)	-5.4 (3.8, -13.9, 0.9)
Race (n, %)					
Caucasian	97 (75)	57 (70)	40 (83)	59 (73)	38 (79)
Black	5 (4)	3 (4)	2 (4)	2 (2)	3 (6)
Asian	11 (9)	9 (11)	2 (4)	7 (9)	4 (8)
Other	1 (1)	-	1 (2)	-	1 (2)
Not reported	15 (12)	12 (15)	3 (6)	13 (16)	2 (4)
Ethnicity (n, %)					
Hispanic	27 (21)	22 (27)	5 (10)	24 (30)	3 (6)
Not Hispanic	86 (67)	49 (60)	37 (77)	48 (59)	38 (79)
Not reported	16 (12)	10 (12)	6 (13)	9 (11)	7 (15)
Comorbidities (n, %)	86 (67)	55 (68)	31 (65)	53 (65)	33 (69)
Hypertension	39 (30)	22 (27)	17 (35)	25 (31)	14 (29)
Diabetes mellitus					
Study Eye (OD or OS)	71 OD (55) 58 OS (45)	47 OD (58) 34 OS (42)	24 OD (50) 24 OS (50)	46 OD (57) 35 OS (43)	25 OD (52) 23 OS (48)
Mean Baseline IOP (SD, Min, Max)	17.2 (4.5, 8, 33)	14.5 (2.4, 8, 18)	21.8 (3.4, 19, 33)	16.4 (4.6, 8, 33)	18.6 (4.2, 12, 31)
Mean Baseline Medications (SD, Min, Max)	1.8 (1.3, 0, 4)	1.7 (1.3, 0, 4)	1.9 (1.3, 0, 4)	1.7 (1.3, 0, 4)	1.9 (1.3, 0, 4)
Previous MIGS implant (n, %)	8 (6.2)	3 (3.7)	5 (10.4)	0 (0)	8 (16.7)
Previous ALT or SLT (n, %)	30 (23.3)	17 (21.0)	13 (27.1)	12 (14.8)	18 (37.5)
Previous cycloablation (n, %)	1 (0.8)	0 (0)	1 (2.1)	0 (0)	1 (2.1)

POAG = Primary open angle glaucoma, PXG = Pseudoexfoliative glaucoma, PG = Pigmentary glaucoma,
SD = standard deviation, IOP = intraocular pressure
*P-value from Fisher's Exact Test. Comparison between all Standalone and all +Cataract. Race-Ethnicity P-value was for percentage Caucasian-non Hispanic between all +Cataract and all Standalone.

Effectiveness Results

Descriptive statistics were assessed over time for the subgroup of patients who met the entry criteria of the literature control (i.e. a baseline IOP ≥ 16 mmHg).

TABLE 2. OMNI + Cataract and Standalone Results
(Subgroup using the Lewis 2007 eligibility, baseline IOP ≥ 16 mmHg)

	+Cataract			Standalone		
Visit	Mean IOP ± SD	Range	n	Mean IOP ± SD	Range	n
Baseline	19.5 ± 3.8	16.0-33.0	45	20.0 ± 3.6	16.0-31.0	38
1 month	15.7 ± 4.0	6.7-25.0	44	15.3 ± 4.4	8.0-27.0	36
6 month	15.1 ± 2.9	10.0-22.0	40	15.6 ± 3.0	9.0-20.0	37
12 month	15.2 ± 3.0	10.0-22.0	42	15.3 ± 2.7	7.0-19.5	36

TABLE 3. Number of Medications Required Over Time (ROMEO – All patients)

Visit	Mean ± SD	Range	n
Baseline	1.8 ± 1.3	0-4	129
1 month	1.3 ± 1.3	0-5	125
6 month	1.1 ± 1.2	0-5	115
12 month	1.1 ± 1.2	0-5	120

A post-hoc responder analysis was also performed to assess the proportion of patients who experienced a ≥ 20% reduction in IOP at Month 12, no increase in medication, no secondary surgery. Refer to Table 4 for results in patients who had OMNI performed as a Standalone procedure and Table 5 for results in patients who had OMNI performed in conjunction with cataract surgery.

TABLE 4. Proportion of Standalone Subjects with ≥ 20% Reduction in IOP at Month 12, no increase in medication, no secondary surgery

Group	n	Proportion
Pre-op IOP > 18 mmHg	14/24	58.3%
Pre-op IOP ≤ 18 mmHg	4/24	16.7%*
All Standalone	18/48	37.5%*
All meeting Lewis criteria (Pre-Op IOP ≥16 mmHg)	16/35	45.7%*

*20% responder analysis is not appropriate for patients with baseline IOP ≤ 18 mmHg because baseline IOP was controlled.

TABLE 5. Proportion of +Cataract Subjects with ≥ 20% Reduction in IOP at Month 12, no increase in medication, no secondary surgery

Group	n	Proportion
BL > 18 mmHg	15/24	62.5%
BL ≤ 18 mmHg	10/57	17.5%*
All Combined with cataract	25/81	30.9%*
All meeting Lewis criteria (BL ≥16 mmHg)	20/46	43.5%*

*20% responder analysis is not appropriate for patients with baseline IOP ≤ 18 mmHg because baseline IOP was controlled.

Adverse Events

Adverse events (AE) were reported for the study eye only. AE were classified as intraoperative or postoperative. All reported AE were non-serious. 57 out of 129 patients (44.2%) had one or more AE, 72 of 129 (55.8%) had no AE. The number and the percent of reported AE of a given type is summarized in Table 6.

TABLE 6. Adverse Events, by Procedure Sub-Group

Adverse Event	Standalone (N= 48) n (%)	+Cataract (N= 81) n (%)	ALL Adverse Events (N= 129) n (%)
Posterior capsule opacity	5 (10.4)	14 (17.3)	19 (14.7)
Mild anterior chamber inflammation	6 (12.5)	8 (9.9)	14 (10.9)
Cystoid macular edema	3 (6.3)	4 (4.9)	7 (5.4)
Corneal edema	2 (4.2)[1]	4 (4.9)[2]	6 (4.7)
IOP increase ≥ 10 mmHg above baseline >30 days postoperative	3 (6.3)	3 (3.7)	6 (4.7)
Hyphema > 1 mm	2 (4.2)	3 (3.7)	5 (3.9)
Worsening of visual field mean deviation ≥ 2 dB	3 (6.3)	1 (1.2)	4 (3.1)
BCVA loss of ≥ 2 lines Snellen at or after 3 months post-op	2 (4.2)	1 (1.2)	3 (2.3)
Cataract surgery complication	1 (2.1)[3]	1 (1.2)[4]	2 (1.6)
Choroidal effusion	0	1 (1.2)	1 (0.8)
Macular degeneration (dry)	1 (2.1)	0	1 (0.8)
Epiretinal membrane peel	1 (2.1)	0	1 (0.8)
Ocular allergic reaction	0	1 (1.2)	1 (0.8)
Posterior vitreous detachment	0	1 (1.2)	1 (0.8)
Vitreous hemorrhage	1 (2.1)[5]	0	1 (0.8)
Cyclodialysis	0	1 (1.2)	1 (0.8)
Lid edema	1 (2.1)	0	1 (0.8)
Late hypotony	0	1 (1.2)[6]	1 (0.8)
Loss of light perception	0	0	0
Chronic anterior iritis as defined in the FDA MIGS guidance	0	0	0
Total	**31**	**43**	**74**

1 One subject developed corneal edema at 4-6 months post-procedure which was noted to have resolved one year later.
2 Pre-existing Fuch's dystrophy in one subject which worsened required a DSAEK.
3 AE was an IOL dislocation from prior cataract surgery.
4 AE was lens fragment.
5 Vitreous hemorrhage verbatim description was "peripheral retinal hemorrhage" and resolved without treatment in 32 days by the Investigator.
6 One subject underwent post-surgical anterior chamber reformation with Healon viscoelastic fluid for a shallow chamber with failed laser cycloplexy for a related cyclodialysis cleft; multiple paracentesis was performed to remove viscoelastic causing an IOP spike and subsequent surgical cycloplexy to repair the cleft. Small choroidal effusions resolved with closure of the cleft.

Secondary Surgical Interventions

Nine patients (7.0%) required a secondary surgical intervention for IOP in the medical judgment of the Investigator. Time to failure analysis is provided in Section 11.2.3, above. There were 4 SSI in the +cataract group (4.9%) and 5 in the standalone group (10.4%). The reinterventions were SLT (3, 33%), glaucoma drainage device (tube or valve) (3, 33%), trabeculectomy including Express device (2, 22%), and paracentesis (1, 11%).

In addition to secondary surgical intervention for IOP, two subjects underwent additional interventions in the follow-up period, one in the standalone OMNI group (N= 1/48, 2.1%) and one in combined Omni with cataract extraction group (N= 1/81, 1.2%). The subject in the standalone OMNI group had pre-existing Fuch's dystrophy and experienced a worsening requiring a Descemet Stripping Automated Endothelial Keratoplasty (DSAEK) procedure which resolved the corneal edema. The second subject who underwent a combined cataract extraction and OMNI procedure was noted to have a shallow, but not a flat chamber. Small choroidal effusions were noted as well as a cyclodialysis cleft which was not notable on exam due to the shallow chamber. Chamber reformation using Healon was performed, partially for therapeutic reasons but mostly to facilitate view of the angle. This allowed gonioscopic visualization of the angle which revealed the location of the cleft and laser cycloplexy was attempted to close the cleft. An IOP spike ≥ 10 mmHg above baseline was secondary to the Healon injection and paracentesis were performed to remove viscoelastic material from the eye. When laser cycloplexy failed to close the cleft, the surgeon performed a surgical cycloplexy. Small choroidal effusions resolved with closure of the cleft.

GENERAL INFORMATION ABOUT THE OMNI® EDGE SURGICAL SYSTEM

The OMNI Edge microcatheter can be advanced/retracted multiple times with a maximum length of 20 mm per cycle.

Note: The first two advancement cycles dispense the complete volume of viscoelastic fluid. Subsequent cycles do not dispense viscoelastic.

The OMNI Surgical System can deliver approximately 10.5 microliters of viscoelastic in each 20 mm cycle. The total volume of viscoelastic that can be delivered by the OMNI Edge Surgical System is approximately 21 microliters.

Directions for Use

1. **Removing OMNI Edge from its packaging**
   a. Open the sterile lid barrier from the tray using the exposed edges.
   b. Remove OMNI Edge from the packaging tray, making sure to remove the distal cannula end from the package first.

      Caution: Handle the OMNI Edge device carefully to avoid kinking or damaging the cannula. Avoid touching the cannula tip to any unintended surfaces as this may damage or compromise cleanliness of the tip.
   c. Inspect the OMNI Edge device for damage.

      Caution: If the OMNI Edge device appears damaged, do not use it.
   d. Set OMNI Edge aside within the sterile field.

2. **Priming OMNI Edge with viscoelastic fluid**

To use OMNI Edge for viscodilation, the device must first be primed with commercially available cohesive viscoelastic fluid by following the instructions below.

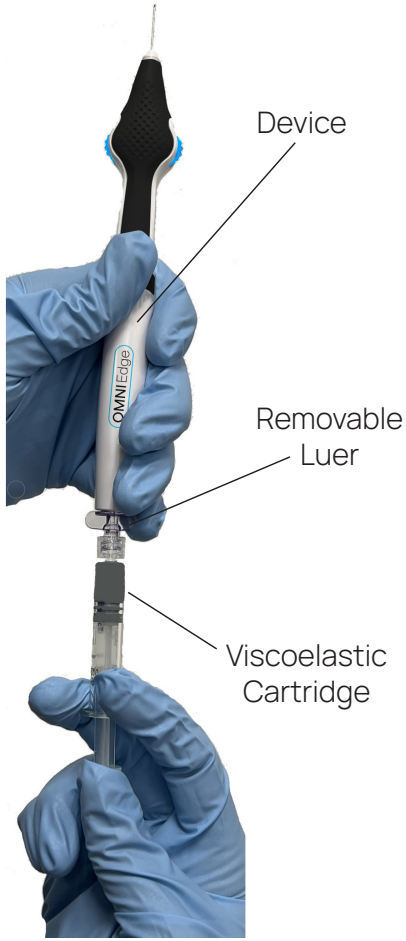
   a. Fully flush the viscoelastic cartridge with viscoelastic fluid prior to attaching it to the Luer fitting.

      Caution: The OMNI Edge is indicated only for use with cohesive viscoelastic fluid. Do not use with dispersive viscoelastic fluid.

      Caution: Do not remove the luer from OMNI Edge before priming the device with viscoelastic fluid.

   b. Directly attach the viscoelastic cartridge to the standard Luer fitting. Make sure to only rotate the OVD cartridge clockwise, in order to avoid inadvertent removal of the luer fitting. Hold the OMNI Edge device, now connected to a viscoelastic cartridge, UPRIGHT before proceeding.

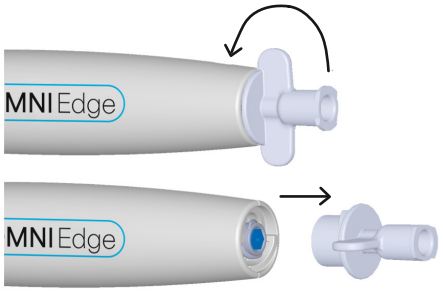
      Caution: Do not use nozzles or needles, including those provided with commercial viscoelastics themselves, as these may damage the device.
   c. Keeping one hand on OMNI Edge to stabilize the device, hold the combined OMNI Edge and viscoelastic cartridge pointing UPWARD, apply constant pressure to inject viscoelastic into the proximal end of OMNI Edge until SLOW viscoelastic flow is visualized coming from the cannula tip. Once viscoelastic is seen flowing out of the OMNI Edge cannula tip, the device is fully primed with viscoelastic and air should now be fully flushed from the device.



Caution: When priming the device, ensure that injection of viscoelastic into the device is done slowly with constant pressure (over approximately 10 seconds).

d. Remove the viscoelastic cartridge and removable luer fitting from the proximal end of the OMNI Edge device by rotating the OVD cartridge counterclockwise. If the luer fitting did not yet remove from the OMNI Edge device handle, use the wing features to unthread the luer fitting from the device by rotating counter-clockwise.

Note: The removable luer fitting may be removed in conjunction with the viscoelastic cartridge.



e. The OMNI Edge is now ready to use in the eye.

3. Using OMNI Edge to Catheterize and Viscodilate Schlemm's Canal (Canaloplasty)

Caution: Surgical gloves should be dry while using the OMNI Edge device. Viscoelastic fluid in particular on the surgeon's gloves can compromise the surgeon's ability to effectively rotate the advancement wheel.

a. Consider administering preoperative or intraoperative miotics to improve anterior chamber angle visibility.

b. Ensure that a pre-existing corneal or scleral wound at least 2 mm wide is created.

Caution: Do not use the cannula tip to make an incision in the eye to access the anterior segment.

Caution: Avoid touching the cannula tip to any unintended surfaces as this may damage or compromise cleanliness of the tip.

c. Carefully and slowly advance the cannula into the anterior chamber through the existing wound.

Warning: Maintain direct microscopic or gonioscopic visualization of the cannula and microcatheter tip at all times during the procedure to avoid inadvertently damaging intraocular structures.

d. Ensure a maintained anterior chamber. For example, viscoelastic or continuous balanced salt solution irrigation can be used.

Caution: Mixing of quaternary ammonium salts, such as benzalkonium chloride, with sodium hyaluronate (viscoelastic fluid) results in the formation of a precipitate. Use of fluids containing such salts during ocular irrigation must be avoided if using the OMNI Edge device loaded with sodium hyaluronate (viscoelastic fluid).

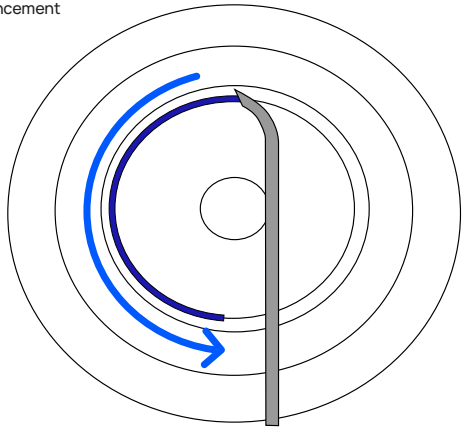
e. While avoiding touching the cannula tip to the wound or any other surface, advance the cannula tip into the anterior chamber and towards the iridocorneal angle under direct microscopic (or gonioscopic) visualization.

f. When nearing the iridocorneal angle (and thus the trabecular meshwork), apply a gonioscope or gonioprism to the cornea to visualize the angle. A viscous fluid may be used to couple the gonioscope or gonioprism to the cornea, as recommended by the gonioscope manufacturer.

g. Under gonioscopic visualization, identify the anatomic landmarks of the anterior chamber angle: ciliary body, scleral spur, trabecular meshwork, and Schwalbe's line.

h. With the trabecular meshwork visualized, approach the angle with the sharp device tip, and pierce the meshwork at an angle of 15-30 degrees. After piercing the meshwork and entering the canal, adjust the angle of the device to approximately 0-5 degrees. Hold the device tip securely against the anterior chamber angle to properly guide the microcatheter into the canal and also to prevent any movement and to maintain intracameral stability of the device at this point.

180-degree Microcatheter Advancement



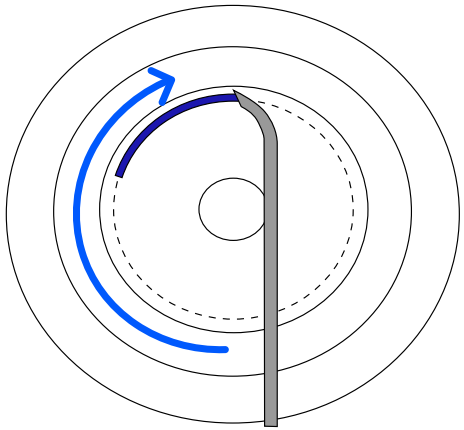
i. While holding the cannula securely against the angle, advance the OMNI Edge microcatheter slowly into Schlemm's canal by gently rotating the blue wheel on the top side of the device towards the front of the device (away from you). Ensure that the lower wheel is free to rotate. Advance the microcatheter for up to 180 degrees of Schlemm's canal, or approximately 20 mm of circumferential canal travel, until the wheel cannot be rotated further.

Warning: Maintain gonioscopic visualization of the cannula and microcatheter to facilitate controlled advancement and retraction and to avoid kinking of the microcatheter, cutting of the trabecular meshwork, false passages, and/or damage to intraocular structures.

Caution: The microcatheter should be advanced slowly and the cannula tip must be positioned to allow the microcatheter to travel freely into the canal, without becoming kinked or bent. If significant resistance to advancement is encountered, slowly and carefully retract the microcatheter by rotating the wheel towards you.

j. Once up to 180 degrees of Schlemm's canal has been catheterized and the wheel cannot be rotated further, rotate the wheel in the opposite direction towards the rear of the device (towards you) to retract the microcatheter out of the canal and back into the cannula. As the microcatheter is being retracted, a precise volume of viscoelastic is delivered from the tip of the microcatheter to provide transluminal viscodilation along the length of Schlemm's canal. Upon complete retraction of the microcatheter, a 180-degree canaloplasty has been completed and a total of 10.5 microliters of viscoelastic fluid has been dispensed.

180-degree Microcatheter Retraction



Note: The user should expect to apply more rotational force on the wheel to retract the microcatheter back into the cannula and dispense viscoelastic fluid than the force required to simply advance the microcatheter.

Caution: During retraction, maintain a coaxial position between the microcatheter and cannula and retract the microcatheter slowly. Attempting to retract the microcatheter at an acute angle to the cannula and/or retracting too quickly can kink or damage the microcatheter and can increase the wheel resistance.

k. Carefully withdraw the cannula from the corneal incision. If the chamber has shallowed or blood reflux reduces visibility, place additional viscoelastic into the anterior chamber or perform irrigation.

Warning: Remove the cannula from the corneal incision under visual control to prevent corneal abrasion.

l. The other 180 degrees of Schlemm's canal may be catheterized and viscodilated to complete a full 360-degree canaloplasty. To do so, rotate the device to orient the cannula tip outside of the eye to prepare the device for entry into the second 180 degrees of Schlemm's canal. Repeat the previous steps.

Warning: Do not attempt to rotate the cannula 180-degrees within the anterior segment. Inadvertent contact with ocular tissue may damage ocular structures.

4. **Using OMNI Edge to Re-Catheterize Schlemm's Canal and Cut Trabecular Meshwork (Trabeculotomy)**

Caution: Surgical gloves should be dry while using the OMNI Edge device. Viscoelastic fluid on the surgeon's gloves in particular can compromise the surgeon's ability to effectively rotate the wheel.

a. After viscodilation of Schlemm's Canal, carefully and slowly re-introduce the cannula into the anterior chamber through the existing corneal or scleral wound.

Warning: Maintain direct microscopic or gonioscopic visualization of the cannula and microcatheter tip at all times during the procedure to avoid inadvertently damaging intraocular structures.

Caution: Do not use the distal end of the cannula tip to make an incision in the eye to access the anterior segment.

Caution: Avoid touching the cannula tip to any unintended surfaces as this may damage or compromise cleanliness of the tip.

b. Ensure a maintained anterior chamber. For example, viscoelastic or continuous balanced salt solution (BSS) irrigation can be used.

c. While avoiding touching the cannula tip to the wound or any other surface, advance the cannula tip into the anterior chamber and towards the iridocorneal angle under direct microscopic (or gonioscopic) visualization.

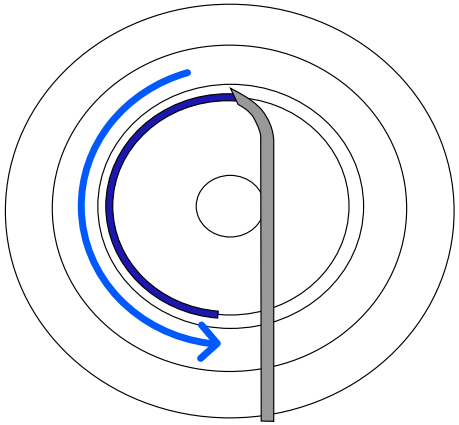
d. When nearing the iridocorneal angle (and thus the trabecular meshwork), apply a gonioscope or gonioprism to the cornea to visualize the angle. A viscous fluid may be used to couple the gonioscope or gonioprism to the cornea, as recommended by the gonioscope manufacturer.

e. Under gonioscopic visualization, identify the anatomic landmarks of the anterior chamber angle: ciliary body, scleral spur, trabecular meshwork, and Schwalbe's line.

f. With the trabecular meshwork directly visualized with a gonioscope, approach the angle with the cannula tip, and pierce the meshwork at an angle of 15-30 degrees. Alternatively, the microcatheter can enter the pre-existing wound used for canaloplasty. After piercing the meshwork and entering the canal, hold the cannula securely against the anterior chamber angle, at an angle of approximately 0-5 degrees, to properly guide the tip of the flexible microcatheter into the canal and also to prevent any movement of the device at this point.

g. While holding the cannula securely against the angle, advance the OMNI Edge microcatheter slowly into Schlemm's canal by gently rotating the blue wheel on the top side of the device towards the front of the device (away from you). Ensure that the lower wheel is free to rotate. Advance the microcatheter for up to 180 degrees of Schlemm's canal, or approximately 20 mm of circumferential canal travel, until the wheel cannot be rotated further.

180-degree Microcatheter Advancement



Caution: The microcatheter should be advanced slowly and the cannula tip must be positioned to prevent the microcatheter from being kinked or bent. If any resistance to advancement is encountered, slowly and carefully retract the microcatheter by rotating the wheel toward you.

Warning: Maintain gonioscopic visualization of the cannula and microcatheter to facilitate controlled advancement and retraction to avoid kinking of the microcatheter, false passages, and/or damage to intraocular structures.

h. If retraction of the microcatheter during use is desired, rotate the wheel towards the rear of the device (towards you). Ensure that the lower wheel is free to rotate.

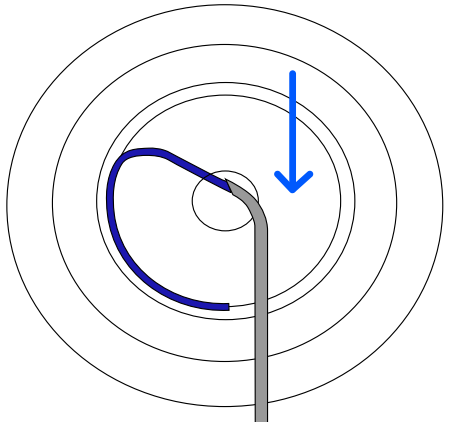
Caution: In the event retraction of the microcatheter is required, maintain a coaxial position between the microcatheter and the cannula tip during retraction. Attempting to retract the microcatheter with an acute angle can kink or damage the microcatheter and can increase the wheel resistance.

Caution: If retraction of the microcatheter is required after the goniotomy has been initiated, then reposition the system to maintain a coaxial position between the microcatheter and the cannula.

i. With the microcatheter resting in the canal, carefully remove the cannula from the corneal incision and out of the eye causing the microcatheter to cut the trabecular meshwork to perform the trabeculotomy.

Warning: Visualize the corneal incision to manage cannula and microcatheter removal and to prevent corneal abrasion.

Performing the Trabeculotomy



j. While removing the cannula from the corneal incision to cut the trabecular meshwork, it is permissible to reduce the microcatheter length between the trabecular meshwork and the cannula tip by slowly retracting the microcatheter back into the cannula. This is achieved by rotating the wheel towards the rear of the device (towards you) while keeping the microcatheter coaxial with the cannula.

Caution: While performing a trabeculotomy, excessive exposed length of microcatheter within the anterior segment may kink or damage in the microcatheter.

Caution: While performing a trabeculotomy, and concurrently retracting the microcatheter into the cannula, be mindful to keep the microcatheter coaxial with the cannula and do not apply extreme tension to the microcatheter. This may result in kinking or damaging the microcatheter.

k. Carefully remove the device from the eye.

l. Upon complete removal of the cannula and microcatheter from the eye, retract the microcatheter back into the cannula by rotating the wheel toward the rear of the device (toward you).

m. If additional trabeculotomy is desired, perform a trabeculotomy in the other 180 degrees of Schlemm's Canal to complete up to a 360-degree trabeculotomy. If the chamber has shallowed or blood reflux reduces visibility, place additional viscoelastic into the anterior chamber or perform irrigation.

n. Outside the eye, rotate the OMNI Edge device 180-degrees so that the cannula tip faces the opposite direction.

Warning: Do not attempt to rotate the cannula 180-degrees within the anterior segment. Inadvertent contact with ocular tissue may damage ocular structures.

o. Carefully and slowly advance the distal end of the cannula into the anterior chamber through the pre-existing corneal wound.

Caution: If any resistance to advancement is encountered, slowly and carefully retract the microcatheter by rotating the wheel toward you.

p. Repeat the previously described steps to perform the second trabeculotomy (up to 180-degrees), if desired.

Warning: Maintain visualization of the cannula tip at all times during use to avoid inadvertently damaging intraocular structures.

5. **Completing the Procedures**

a. Irrigate the anterior chamber with balanced salt solution (BSS) through the corneal wound manually or with automated irrigation/aspiration to remove viscoelastic and any refluxed blood. If viscoelastic was used to maintain the anterior chamber, it should be irrigated from the eye to avoid an acute rise in intraocular pressure.

b. Reform the anterior chamber with balanced salt solution (BSS), as needed, to achieve physiologic pressure.

c. Ensure that the corneal or scleral incision is sealed; use a suture if necessary.

d. Ensure that the proper antibiotic and/or anti-inflammatory is used postoperatively, as is customary with intraocular surgery.

e. Consider using a miotic, such as carbachol or pilocarpine, at the conclusion of surgery to avoid synechiae formation.

6. **Postoperative Instructions**

Patients should be managed postoperatively for intraocular pressure increases that may occur in the early postoperative period. If postoperative intraocular pressure is high, initiate the appropriate management of raised intraocular pressure, including medication or surgery.

Patients should be advised to keep their head elevated for 72 hours and to not sleep on the side where they had surgery to avoid hyphema formation.

Consider using a miotic (e.g. pilocarpine) for 2 weeks post-operatively.

Potential Adverse Events

Adverse events that may be reasonably associated with the use of the OMNI® Edge Surgical System in the eye include but are not limited to the following: anterior chamber shallowing, severe, prolonged, or persistent intraocular inflammation including toxic anterior chamber segment syndrome (TASS), endophthalmitis or other ocular infection, aqueous misdirection, Descemet's membrane tear or detachment, intracorneal hematoma, choroidal effusion, suprachoroidal hemorrhage, corneal decompensation, corneal injury, corneal edema or opacification, unintended trabeculotomy, cyclodialysis cleft, hyphema, hypopyon, hypotony, hypotony maculopathy, IOL dislocation, cataract formation, iris injury, tear, or iridodialysis, loss of vitreous, perforation of sclera, posterior capsular bag rupture, proliferative vitreoretinopathy, pupillary block, pupillary membrane formation, retinal detachment, retinal dialysis, retinal flap tears, secondary surgical intervention, including but not limited to glaucoma surgery, and vitreous hemorrhage.

ADVERSE EVENT REPORTING

Adverse events and/or potentially sight-threatening complications that are reasonably associated with the use of the OMNI Edge must be reported to Sight Sciences, Inc.

Sight Sciences, Inc.
4040 Campbell Ave.
Suite 100
Menlo Park, CA 94025
Telephone: (877) 266-1144

How Supplied

The OMNI Edge Surgical System is a sterile, disposable, single-use surgical device. The device is packaged in a protective packaging that secures it and protects the delicate cannula tip. The OMNI Edge has been sterilized by gamma irradiation.

Catalog Number	Description
1-112	OMNI Edge Surgical System (US)

EXPIRATION DATE

The expiration date on the OMNI Edge package is the sterility expiration date. Sterility is assured if the packaging is not punctured or damaged until the expiration date. OMNI Edge should not be used past the indicated sterility expiration date.

DEVICE DISPOSAL

Dispose of the OMNI Edge following your facility's procedures for sharps and biohazardous waste.

RETURNED GOODS POLICY

Please contact Sight Sciences, Inc.

LABELING

The following symbols are used on the OMNI Edge packaging. The symbols comply with the international standard - ISO 15223-1:2021.

Symbol	Title of Symbol	ISO 7000 Reg. no.	Definition
	Catalogue number	2493	Indicates the manufacturer's catalogue number so that the device can be identified.
	Batch code	2492	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Do not re-use	1051	Indicates a device that is intended for one use.
	Use-by date	2607	Indicates the date (year-month) after which the device is not to be used.
	Manufacturer	3082	Indicates the device manufacturer.
	Sterilized using irradiation	2502	Indicates a device that has been sterilized using irradiation.
	N/A	N/A	For prescription use only.
	Consult instructions for use	1641	Indicates the need for the user to consult the instructions for use.

MANUFACTURER

Sight Sciences
4040 Campbell Ave., Suite 100
Menlo Park, CA 94025

(877) 266-1144
sightsciences.com/omniedge

Sight Sciences®

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