OMNI® ULTRA SURGICAL SYSTEM

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The OMNI® Ultra Surgical System, 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 microcatheter 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® Ultra facilitates the transluminal viscodilation of the circumference of Schlemm's canal and the cutting of up to the full circumference 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® Ultra 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.

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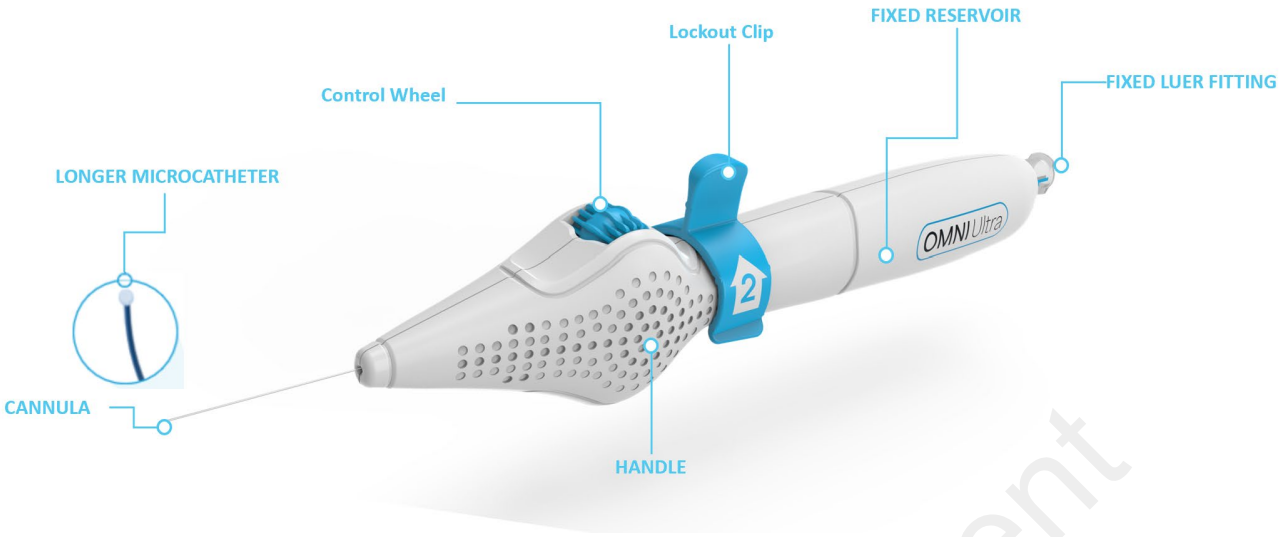


CONTRAINDICATIONS

1. Do not use the OMNI® Ultra 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® Ultra 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. Caution should be used where a prior MIGS implant is present. Do not attempt to advance the microcatheter in an area occupied by the implant.

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. Always maintain direct microscopic or gonioscopic visualization of the cannula tip and awareness of microcatheter tip location 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® Ultra is indicated only for use with cohesive viscoelastic fluid. Do not use with dispersive viscoelastic fluid or viscoadaptive fluids (e.g., Healon 5 OVD).
2. Observe all usual precautions undertaken during intraocular surgery.
3. Use aseptic technique and ensure OMNI® Ultra 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® Ultra cannula carefully to avoid kinking or damaging the cannula or microcatheter.
6. The OMNI® Ultra 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® Ultra 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. Safety and effectiveness was evaluated in a clinical study using a previous version of the OMNI Surgical System. That study did not evaluate the safety and effectiveness in those who are phakic. The incidence of cataract formation or progression, among other possible adverse events, is unknown.
11. Safety and effectiveness was evaluated in a clinical study using a previous version of the OMNI Surgical System; refer to clinical study summary below. In this study, 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 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	72.1	71.9	72.4	70.3	75.0
(SD, Min, Max)	(8.6, 51, 94)	(8.6, 51, 94)	(8.5, 56, 88)	(8.0, 51, 89)	(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	-5.1	-5.1	-4.9	-4.8	-5.4
(SD, Min, Max)	(3.8, -14.4, 9.4)	(3.6, -13.4, 9.4)	(4.0, -14.4, 0.9)	(3.7, -14.4, 9.4)	(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, %)					
Hypertension	86 (67)	55 (68)	31 (65)	53 (65)	33 (69)

Diabetes mellitus	39 (30)	22 (27)	17 (35)	25 (31)	14 (29)
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)

Adverse Event	Standalone (N= 48) n (%)	+Cataract (N= 81) n (%)	ALL Adverse Events (N= 129) n (%)
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® Ultra SURGICAL SYSTEM

The OMNI® microcatheter can be advanced and retracted multiple times. The microcatheter extends a maximum length terminating within the fourth quadrant of the average patient's eye, where each quadrant represents 90 degrees or 3 clock hours.

The OMNI Ultra enables a single pass canaloplasty from a single access point in Schlemm's Canal where the microcatheter may be extended up to the maximum length. Alternatively, segmental treatment is possible via controlled advancement/retraction. For example, a dual pass technique may be used to treat each hemisphere (180 degrees/2 quadrants) in two 6 clock hour passes.

DISPENSING CONTROL

The OMNI® Ultra Surgical System delivers viscoelastic correlated with catheter movement in a motion-synchronized fashion, evenly distributing viscoelastic during microcatheter travel. During a canaloplasty procedure of a full advancement and retraction, the device delivers approximately 6 microliters of viscoelastic during advancement, and during retraction the device delivers approximately 15 microliters of viscoelastic for a total dispense of approximately 21 microliters. Dispensing is achieved for one full advancement and retraction, in a single pass through one full travel cycle. In the case of segmental treatment, delivery of OVD is controlled and motion synchronized to the movement of the finger wheel up to the total dispense of 21 µl (6 µl on advancement, 15 µl on retraction).

Catalog Number	Description	Approx. Advance Dispense Volume	Approx. Retract Dispense Volume	Approx. Total Dispense Volume
1-110	OMNI Ultra Surgical System	6 µl	15 µl	21 µl

DIRECTIONS FOR USE

1. Removing the OMNI® Ultra from its packaging

a. Open the sterile lid barrier from the tray using the exposed edges.

b. Remove the OMNI® Ultra from the packaging tray, making sure to remove the distal cannula end from the package first.

Caution: Handle the OMNI® Ultra 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® Ultra device for damage.

Caution: If the OMNI® Ultra device appears damaged, do not use it.

d. Set OMNI® Ultra aside within the sterile field.

2. Priming the OMNI® Ultra with viscoelastic fluid

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

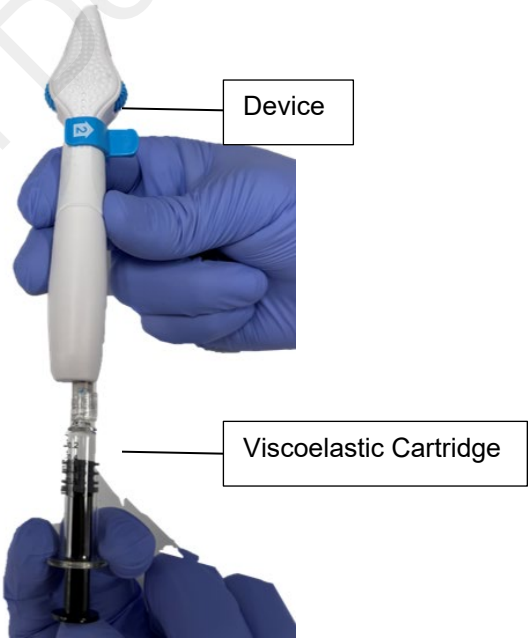
a. Fully flush the viscoelastic cartridge with viscoelastic fluid prior to attaching it to the Luer fitting.

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

b. Directly attach the viscoelastic cartridge to the standard Luer fitting, shown in the image above (also marked with number “1”). Make sure to only rotate the OVD cartridge clockwise. Hold the OMNI® Ultra 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. Hold the combined OMNI® Ultra and viscoelastic cartridge pointing UPWARD, apply constant pressure to inject viscoelastic into the proximal end of the OMNI® Ultra until viscoelastic flow is visualized coming from the cannula tip. Once viscoelastic is seen flowing out of the OMNI® Ultra 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 from the OMNI® Ultra device, the Luer Fitting will remain attached to the device.

e. Remove the blue Lockout clip (also marked with number “2”) by pulling it up and off of the handle in the direction shown by the arrow, the OMNI® Ultra is now ready to use in the eye.

Caution: Once primed, do not prime the OMNI® Ultra device again.

3. Using the OMNI® Ultra to Catheterize and Viscodilate Schlemm’s Canal (Canaloplasty)

Accessing Schlemm’s Canal

Caution: At all procedural steps, surgical gloves should be dry while using the OMNI® Ultra 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. Note the location of the corneal incision as it relates to the access point of the microcatheter into Schlemm’s Canal.

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.

Caution: Ensure that the corneal incision is not in a location that produces excess blood that could impact visualization during the procedure.

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

Warning: Maintain direct microscopic or gonioscopic visualization 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 (BSS) 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 OVD to maintain the anterior chamber.

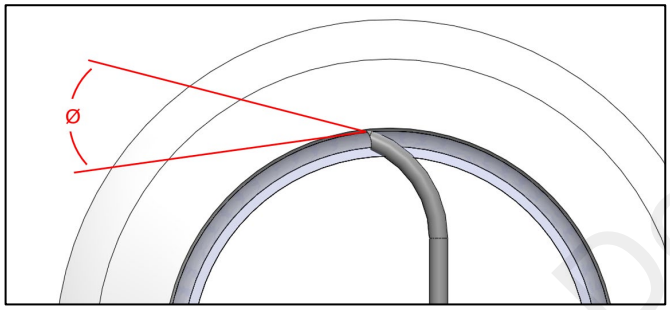
e. While avoiding touching the cannula tip to the wound or any other surface, advance the cannula tip into the anterior chamber and towards the iridocorneal angle under direct microscopic (or gonioscopic) visualization.

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.

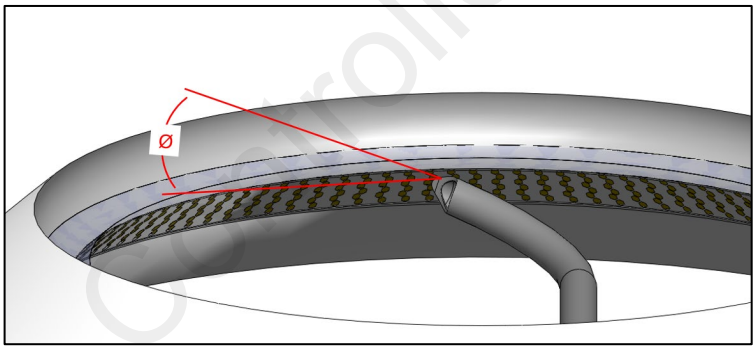
g. Under gonioscopic visualization, identify the anatomic landmarks

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 cannula tip, and gently press in order to pierce the meshwork at an angle of 10-30 degrees from tangential with the canal.



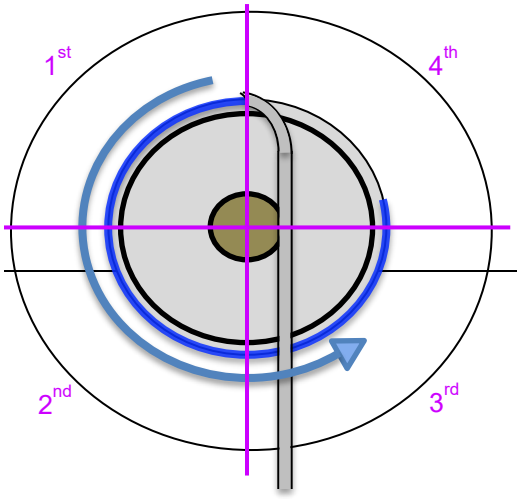
Also, tilt the cannula upwards to an orientation of 15-30 degrees in order to initially bias the microcatheter into the canal. Once the microcatheter has entered the canal, this tilt angle can be adjusted to approximately 0-5 degrees.



Hold the device tip stable against the anterior chamber angle to properly guide the microcatheter into the canal, prevent unintended movement, and to maintain intracameral stability of the device at this point.

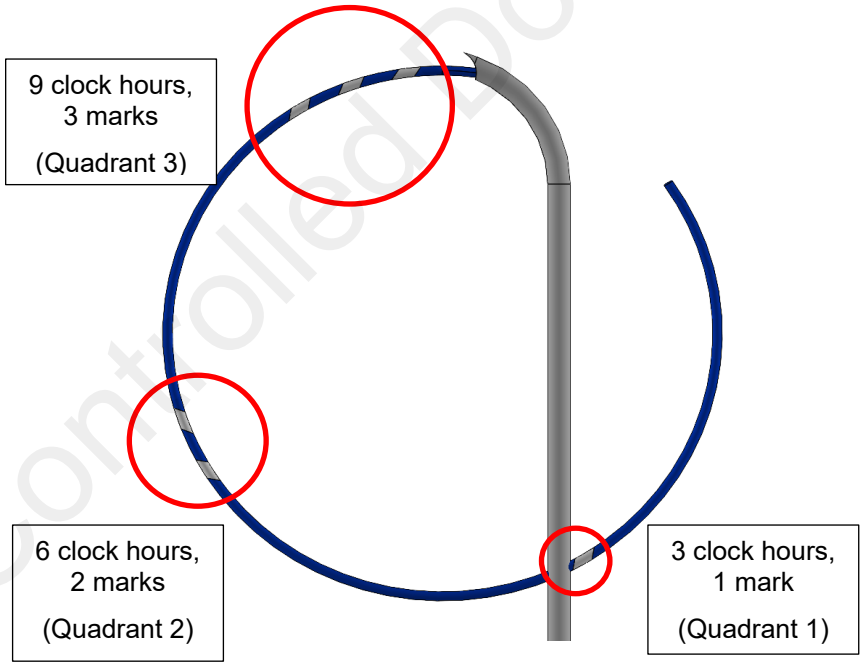
Caution: Avoid excessive angulation of the cannula towards the scleral wall.

Microcatheter Advancement in Schlemm's Canal Quadrants



i. While holding the cannula securely against the angle, advance the OMNI® Ultra microcatheter slowly into Schlemm's canal by gently rotating the 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. The microcatheter has white markings that denote the extent of microcatheter advance during canaloplasty. These markings are present at incremental distances of approximately every three clock hours to denote when the microcatheter tip reaches 3, 6, and 9 clock hours.

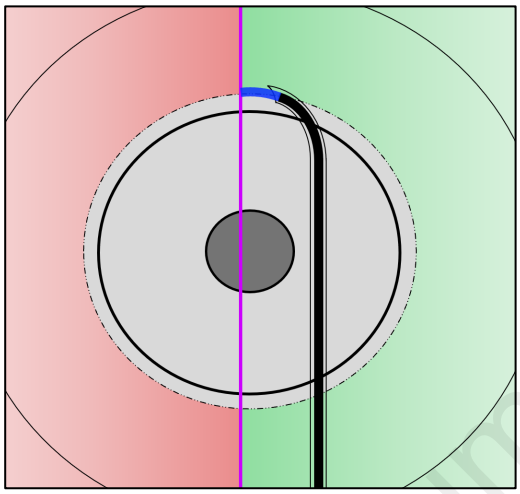
Microcatheter white markings



j. To perform a **Single Pass Canaloplasty (Accessing all 4 quadrants),** advance the microcatheter to its full travel length within Schlemm's Canal. The microcatheter can reach up to the fourth quadrant of Schlemm's Canal. As the microcatheter is being advanced, a small and precise volume of viscoelastic is delivered from the tip of the microcatheter. Ensure the cannula remains adjacent to and behind the goniotomy site and avoids any inadvertent tissue contact. Monitor microcatheter travel to ensure that it remains in Schlemm's Canal.

Warning: Maintain gonioscopic visualization of the cannula as well as awareness of the microcatheter location 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.

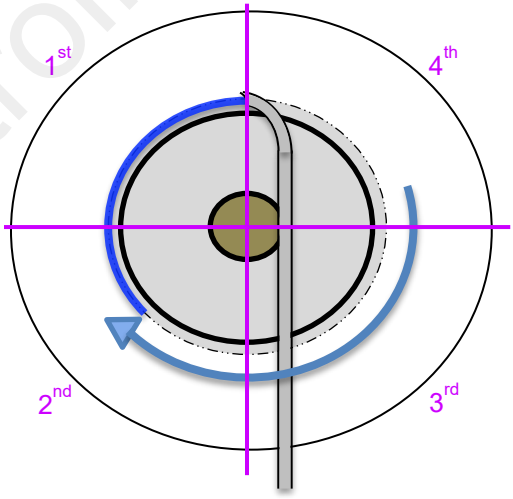
Caution: The microcatheter should be advanced slowly and the cannula tip must be positioned to allow the microcatheter to travel freely into the canal, without becoming kinked or bent. During canaloplasty, avoid forward movement of the cannula beyond the entry point of the microcatheter into Schlemm's Canal, shown in the figure below as the vertical purple line. If significant resistance to advancement is encountered, slowly and carefully retract the microcatheter by rotating the wheel towards you, while maintaining a coaxial position between the microcatheter and cannula.



Caution: Maintain a stable cannula tip within close proximity to the entry site. Maintain a minimal gap between the entry site and cannula tip in order to avoid buckling of the microcatheter. Buckling or looping of the microcatheter could prevent further travel and damage surrounding tissue.

k. Once Schlemm's canal has been microcatheterized up to four quadrants, 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. Rotate the wheel slowly, maintaining finger contact throughout each stroke of retraction and allowing time for viscoelastic dispensation. 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. The canaloplasty is complete once the microcatheter has been fully advanced and retracted.

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.

l. It is recommended to maintain the position of the cannula in preparation for advancing the microcatheter again in order to perform the trabeculotomy. A short length of catheter may optionally be maintained in the canal to stay engaged for re-advancement.

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

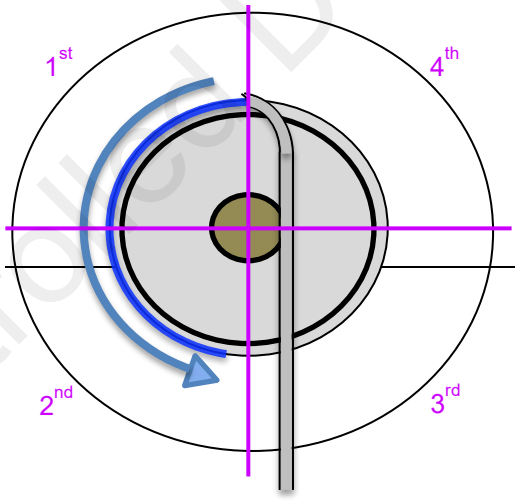
Warning: Do not attempt to rotate the cannula 180-degrees within the anterior segment. Inadvertent contact with ocular tissue may damage ocular structures.

Per Surgeon's Discretion, a Dual Pass Canaloplasty can be performed after performing Steps 1 through 3i with the following Optional Steps:

m. To perform a Dual Pass Canaloplasty (two 180-degree segments) advance the microcatheter until the microcatheter advances within Schlemm's Canal up to 6 clock hours (denoted by 2nd white mark set). The white microcatheter markers provide the user with an indication of the microcatheter travel. As the microcatheter is being advanced, a small and precise volume of viscoelastic is delivered from the tip of the microcatheter. Ensure the cannula remains adjacent to and behind the goniotomy site and avoids any inadvertent tissue contact or potential microcatheter damage, such as kinks. Monitor microcatheter travel to ensure that it remains in Schlemm's Canal.

Warning: Maintain gonioscopic visualization of the cannula as well as awareness of the microcatheter location 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.

Microcatheter Advancement in Schlemm's Canal Quadrants



n. Once Schlemm's canal has been microcatheterized up to the desired distance, 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. Rotate the wheel slowly, maintaining finger contact throughout each stroke of retraction and allowing time for viscoelastic dispensation. 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. The canaloplasty is complete once the microcatheter has been fully advanced and retracted.

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.

o. The other 180 degrees of Schlemm's canal may be catheterized and viscodilated to complete a full 360-degree canaloplasty. To do so, carefully remove the device from the eye via the corneal incision. Outside the eye rotate the device to orient the cannula tip in the opposite direction to perform canaloplasty in the 2nd 180-degree segment of Schlemm's canal. Reintroduce the device into the eye, advance the microcatheter into Schlemm's Canal and dispense viscoelastic fluid.

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

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

4. Using the OMNI® Ultra to Re-Catheterize Schlemm's Canal and Cut Trabecular Meshwork (Trabeculotomy)

a. If access to the anterior chamber and Schlemm's Canal has been maintained from the canaloplasty portion of the procedure, move to step g below. However, if access to the anterior chamber and Schlemm's Canal has not been maintained, 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.

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 OVD to maintain the anterior chamber.

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.

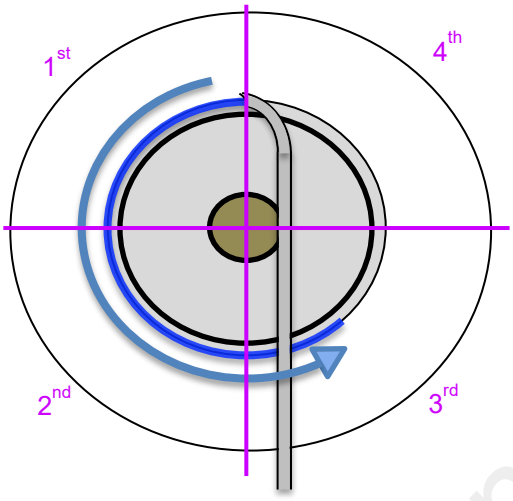
e. Under gonioscopic visualization, identify the anatomic landmarks of the anterior chamber angle: ciliary body, scleral spur, trabecular meshwork, and Schwalbe's line.

f. With the trabecular meshwork directly visualized with a gonioscope, approach the angle with the cannula tip, and gently press in order to pierce the meshwork at an angle of 10-30 degrees from tangential with the canal. Also, tilt the cannula upwards to an orientation of 15-30 degrees in order to initially bias the microcatheter into the canal. Once the microcatheter has entered the canal, this tilt angle can be adjusted to an angle of approximately 0-5 degrees, to properly guide the 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® Ultra microcatheter slowly into Schlemm's canal by gently rotating the 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. In order to perform a trabeculotomy of up to 2 quadrants (6 clock hours), advance the microcatheter tip into the third quadrant of Schlemm's Canal, such as once the 2nd catheter marking is visualized.

h. As with the canaloplasty section of the procedure, after the microcatheter has reached the second hemisphere, the second white mark will appear on the microcatheter as it exits the cannula. These markings are present at incremental distances of approximately three clock hours.

Microcatheter Advancement into Third Quadrant



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.

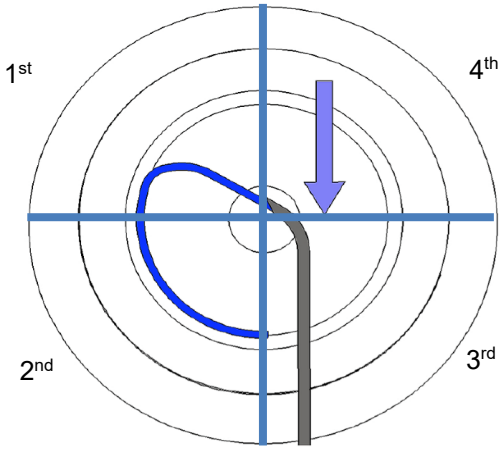
Warning: Maintain gonioscopic visualization of the cannula as well as awareness of microcatheter location to facilitate controlled advancement and retraction to avoid kinking of the microcatheter, false passages, and/or damage to intraocular structures.

Caution: Maintain a stable cannula tip within close proximity to the entry site. Maintain a minimal gap between the entry site and cannula tip in order to avoid buckling of the microcatheter. Buckling of the microcatheter could prevent further travel and damage surrounding tissue.

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, 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 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. Retract the microcatheter until the microcatheter tip is visibly close in proximity to the corneal wound when removing the cannula from the anterior chamber. 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. Optional: If additional trabeculotomy is desired, greater than 2 quadrants, perform a trabeculotomy in the other hemisphere of Schlemm's Canal to complete up to 4 full quadrants of 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® Ultra 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. As was done before, introduce the microcatheter into Schlemm's Canal. While holding the cannula securely against the angle, advance the OMNI® Ultra microcatheter slowly into Schlemm's canal by gently rotating the wheel on the top side of the device towards the front of the device (away from you).

Caution: If any resistance to advancement is encountered, slowly and carefully retract the microcatheter by rotating the wheel toward you, while maintaining a coaxial position between the microcatheter and cannula.

p. Repeat the previously described steps to perform the second trabeculotomy (up to 2 full quadrants), 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. Upon completion of the procedure, examine the anterior segment to visually inspect the treated eye.

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

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

f. Consider using a miotic 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.

POTENTIAL ADVERSE EVENTS

Adverse events that may be reasonably associated with the use of the OMNI® Ultra 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® Ultra 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® Ultra 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® Ultra has been sterilized by gamma irradiation.

Catalog Number	Description
1-110	OMNI Ultra Surgical System

EXPIRATION DATE

The expiration date on the OMNI® Ultra Surgical System label is the date until the product is no longer considered acceptable for use. Sterility is assured if the packaging is not punctured or damaged until the expiration date. The OMNI® Ultra should not be used past the indicated expiration date.

DEVICE DISPOSAL

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

STORAGE REQUIREMENTS

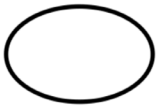
Store the product in a controlled room-temperature environment. Brief (up to 24 hour) exposure down to -18°C or up to +60°C temperature, and minimum 15% to maximum 90% non-condensing humidity is acceptable. Do not use the product if exposed to environmental conditions outside these ranges.

RETURNED GOODS POLICY

Please contact Sight Sciences, Inc.

LABELING

The following symbols are used on the OMNI® Ultra packaging. The symbols comply with the international standard - ISO 15223-1:2021/AMD1:2025.

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.
	Do not resterilize	2608	Indicates that the device should not be re-sterilized after it has been sterilized.
	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.
	Single sterile barrier system	3707	Indicates that there is a single sterile barrier system.
Rx Only	N/A	N/A	For prescription use only.
	Do Not Use if Package is Damaged and Consult Instructions for Use	2606	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Consult instructions for use	1641	Indicates the need for the user to consult the instructions for use.

MANUFACTURER
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Suite 100
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