

OMNI

Implant-Free MIGS, in Standalone or Combo Cataract

OMNI® enables comprehensive glaucoma procedures that target three areas of resistance: Trabecular meshwork, Schlemm's canal, and the collector channels.



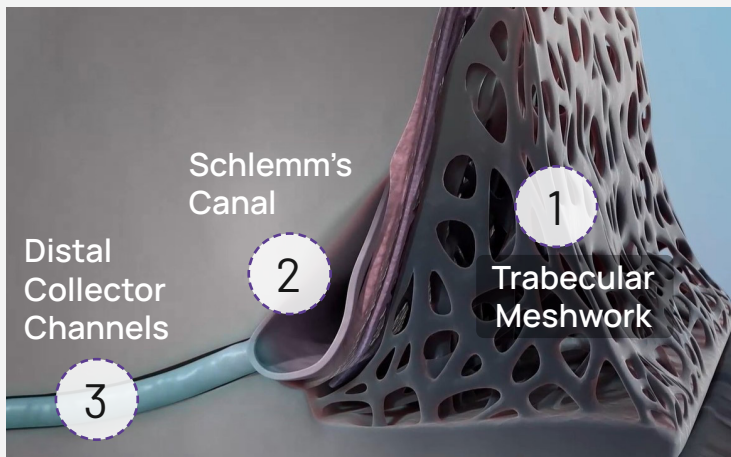
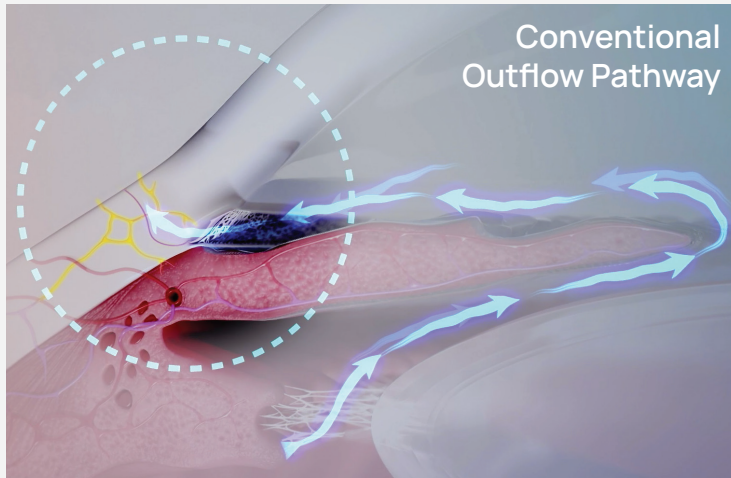
THE CHALLENGE

In eyes with open-angle glaucoma (OAG), identifying where blockage or resistance occurs can be hard.

Targeting the trabecular meshwork alone, or isolating a single point, may not be enough to lower IOP.

Between 50-75% of resistance may be in the trabecular meshwork.^{1,2,3}

Up to 50% of resistance may be in Schlemm's canal and the distal collector channels.^{1,2,3}



1. Grant WM. Experimental aqueous perfusion in enucleated human eyes. Arch Ophthalmol 1963; 69:783-801.

2. Rosenquist R, Epstein D, Melamed S, et al. Outflow resistance of enucleated human eyes at two different perfusion pressures and different extents of trabeculotomy. Curr Eye Res 1989; 8:1233-1240.

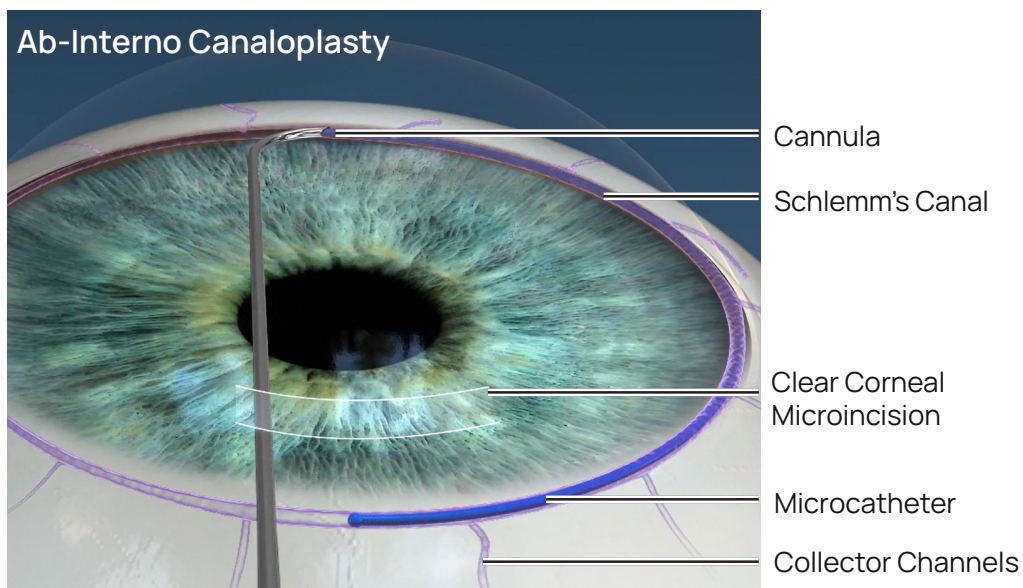
3. Battista SA, Lu Z, Hofmann S, et al. Reduction of the available area for aqueous humor outflow and increase in meshwork herniations into collector channels following acute IOP elevation in bovine eyes.

4. Trabecular meshwork (trabeculotomy), Schlemm's canal (canaloplasty), and collector channels (canaloplasty)

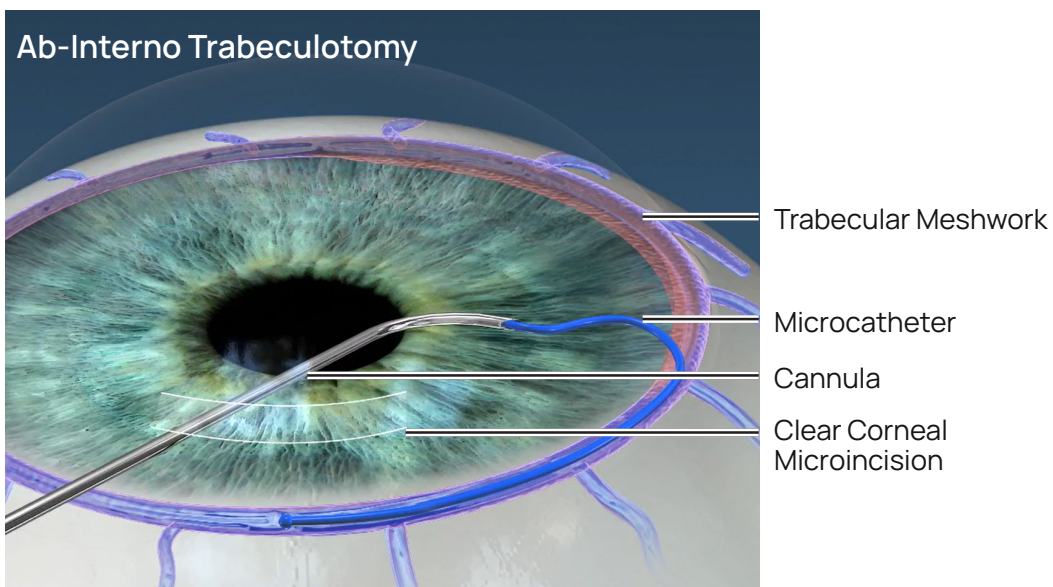
5 Klabe K. Standalone Trabeculotomy and Viscodilation of Schlemm's Canal and Collector Channels in Open-Angle Glaucoma Using the OMNI Surgical System: 24-Month Outcomes. Clinical Ophthalmology 2021;15 3121-3129. 2021 July 20.

THE SOLUTION

Ab-Interno Canaloplasty



Ab-Interno Trabeculotomy



OMNI[®] Surgical System

The first and only MIGS device indicated for canaloplasty and trabeculotomy that;

Enables

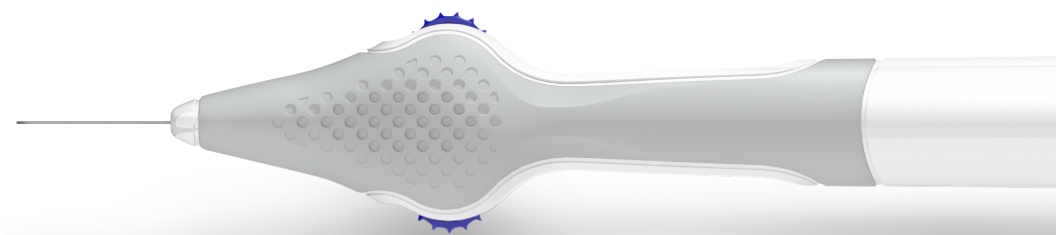
Comprehensive implant-free MIGS procedures, standalone or combined with cataract surgery

Targets

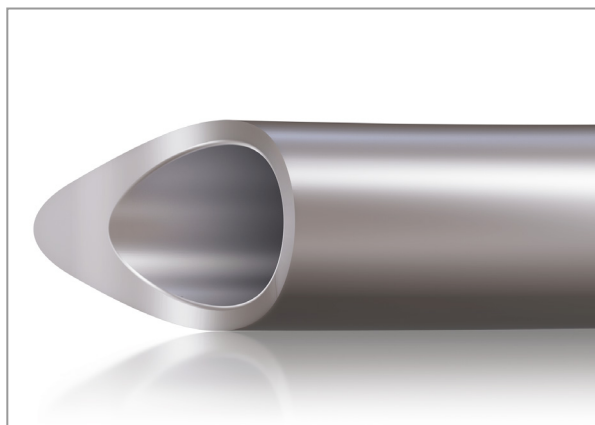
All three areas of resistance to restore natural aqueous outflow⁴

Delivers

Sustained, long-term IOP reduction with the potential to reduce or eliminate medication⁵



ERGO-SERIES : KEY FEATURES



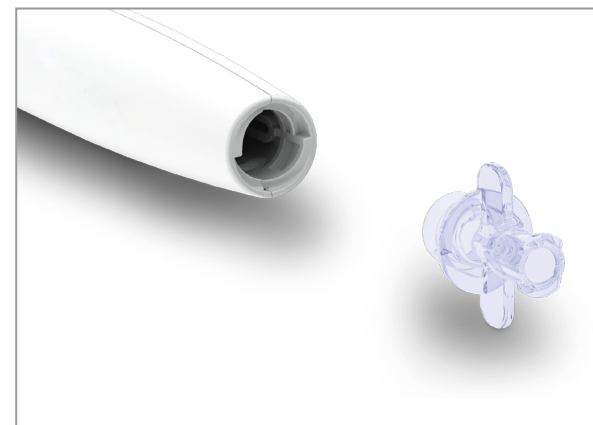
New Cannula Tip Design

The cannula tip has a new profile that enables gentle and precise access to Schlemm's canal while continuing to enable full 360° catheterization associated with the OMNI procedure.



Improved Handle Ergonomics

New enhancements enable surgeons to more easily rotate and position the cannula tip within Schlemm's canal with precise finger rotations versus wrist adjustments.



Simplified OVD Preparation

The handle's viscoelastic Luer connector is now removable and detaches when the viscoelastic cartridge is removed, resulting in more clearance with the surgical microscope.



ERGO-SERIES : KEY FEATURES

Microcatheter

- Length (20mm)
- Diameter of tip (~250 microns)
- Lumen (100 microns)
- Material (Nylon 12)

Finger Wheel

Enhanced prominence and wider ridges for improved tactile feedback

Removable Luer Fitting

Used for direct connection with cohesive OVD cartridge for device preparation

Reservoir

Internal reservoir seamlessly deposits controlled amounts of cohesive OVD as microcatheter is retracted

- Viscoelastic dispensing (11 μL total [5.5 μL /hemisphere])

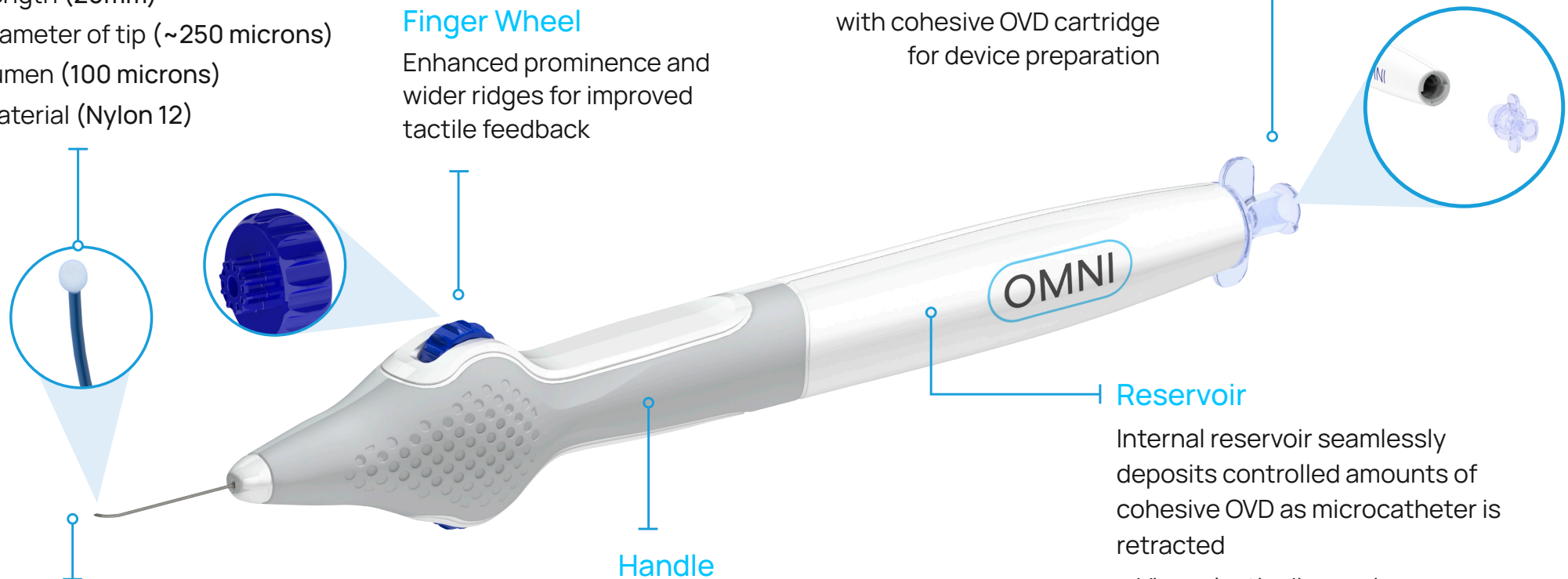
Handle

Comfortable, secure grip for wider variety of grip types and improved stability

Cannula

Bevelled tip allows for easy access into Schlemm's canal

- Diameter (480 microns)



AGIS-7 Findings⁶

< 18mmHg is the target IOP to limit the progression of Glaucoma⁷

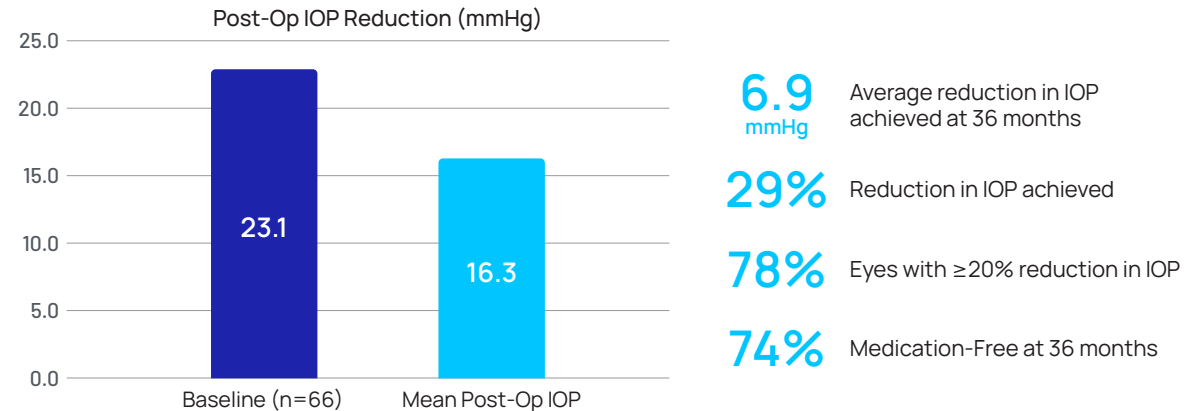
On average, there was zero change in visual fields for patients whose IOP stayed below 18mmHg over 6 years.



THE POWER OF OMNI

GEMINI 36-Month Trial⁸

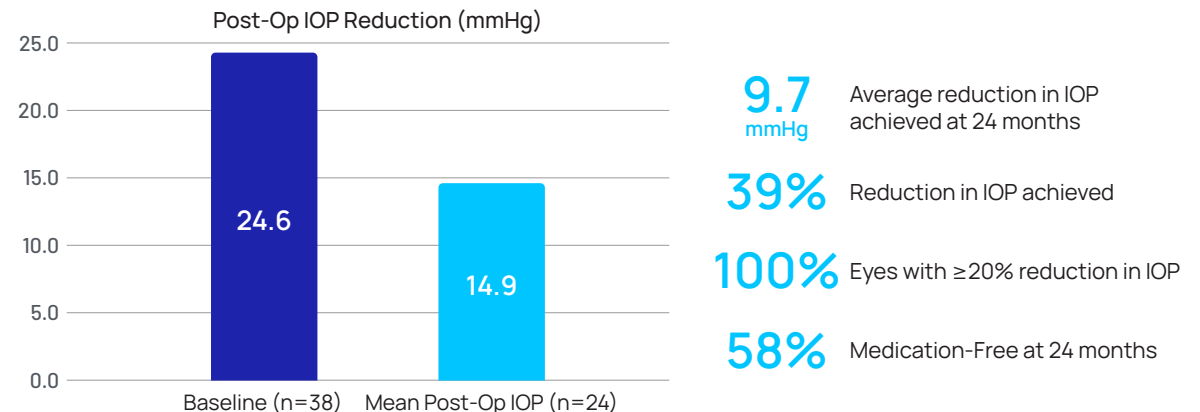
Combined OMNI & Phaco Patient Data



Purpose: To report 36-month efficacy outcomes of 360° canaloplasty and 180° trabeculotomy using the OMNI Surgical System in combination with phacoemulsification.

KLABE 24-Month Study⁹

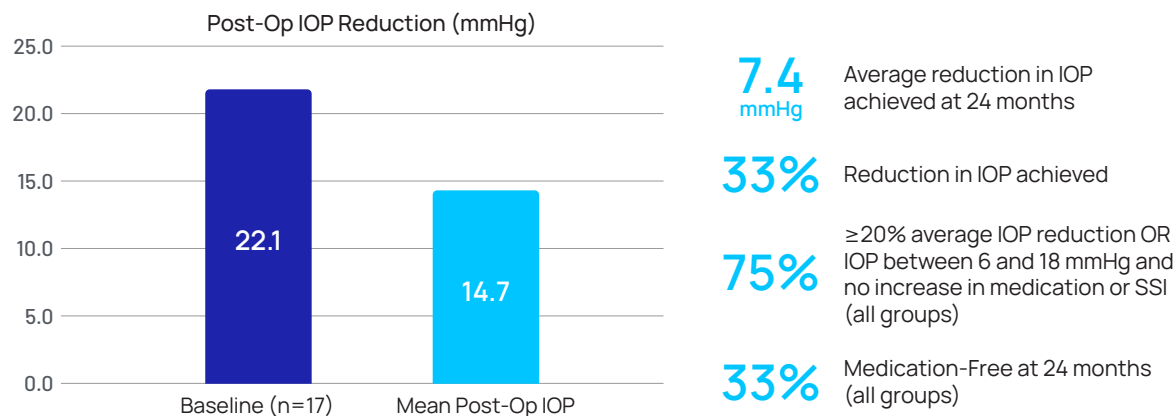
Standalone Patients



Purpose: Intraocular pressure, medication outcomes at 24 months following trabeculotomy & viscodilation using the OMNI Surgical System as a standalone procedure in mild-moderate open-angle glaucoma.

ROMEO 24-Month Study¹⁰

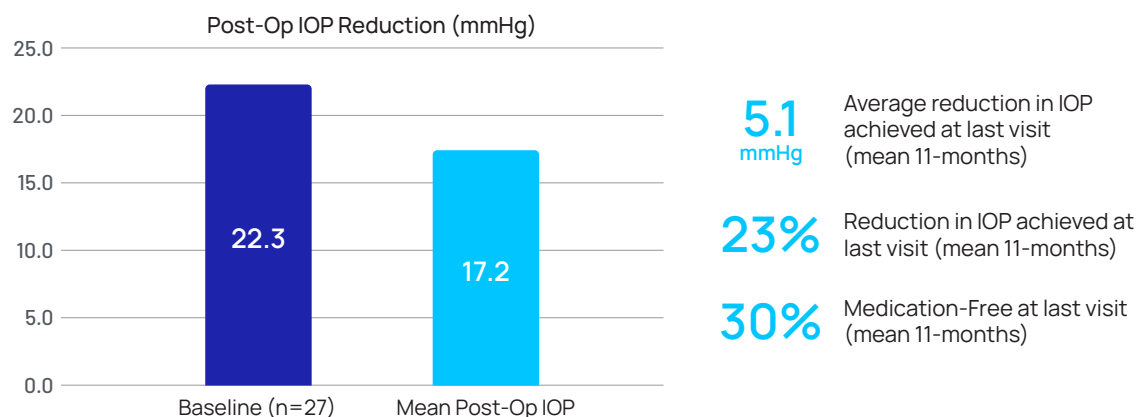
Standalone >18mmHg Subgroup



Purpose: To provide extended safety and effectiveness follow-up for eyes treated with circumferential canaloplasty and trabeculotomy that were included in the 24-month ROMEO study, (mean follow-up 2.1 years – max 3.5 years).

TREY Study¹¹

Standalone Patients (12 stent removals)



Purpose: Evaluate efficacy and safety outcomes for patients treated with canaloplasty and trabeculotomy, (OMNI), previously treated with a trabecular meshwork micro stent (iStent® & iStent® inject).

6. The Advanced Glaucoma Intervention Study (AGIS): 7. The relationship between control of intraocular pressure and visual field deterioration. The AGIS Investigators. Am J Ophthalmol. 2000 Oct;130(4):429-40. doi: 10.1016/s0002-9394(00)00538-9. PMID: 11024415

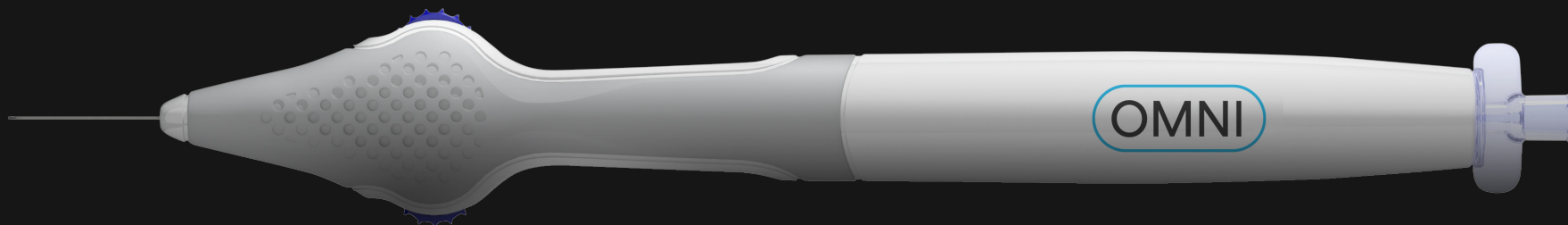
7. As assessed by visual field

8. Greenwood, M, et al. 36-Month Outcomes from the Prospective GEMINI Study: Canaloplasty and Trabeculotomy Combined with Cataract Surgery for Patients with Primary Open-Angle Glaucoma. Clin Ophthalmol, 2023 Dec; 17: 3817-3824

9. Klabe K. Standalone Trabeculotomy and Viscodilation of Schlemm's Canal and Collector Channels in Open-Angle Glaucoma Using the OMNI Surgical System: 24-Month Outcomes. Clinical Ophthalmology 2021;15 3121-3129. 2021 July 20

10. Williamson, B. et al., Canaloplasty and Trabeculotomy with the OMNI System in Patients with Open-Angle Glaucoma: Two-Year Results from the ROMEO Study. Clinical Ophthalmology 2023; 17 1057-1066

11. Terveen DC, Sarkisian SR Jr, Vold SD, Selvadurai D, Williamson BK, Risvedt DG, Bleeker AR, Dhamdhare K, Dickerson JE Jr. Canaloplasty and trabeculotomy with the OMNI(R) surgical system in OAG with prior trabecular microbypass stenting. Int. Ophthalmol. 2022 Oct 113. doi: 10.1007/s10792-022-02553-6. Epub ahead of print. PMID: 36229561.



Learn more at omnisurgical.com

INDICATIONS FOR USE: The OMNI Surgical System is indicated for the catheterization and transluminal viscodilation of Schlemm's canal and the cutting of trabecular meshwork to reduce intraocular pressure in adult patients with open-angle glaucoma.

CONTRAINDICATIONS: Do not use the OMNI in any situations where the 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.

For important product information including cautions and adverse events, please refer to the full Instructions for Use. Contact us at glaucoma@sightsciences.com or visit OMNISurgical.com/international for additional information.

©2024 Sight Sciences, Inc.
05/2024 OM-3208-OUS.v1

OMNI and the Sight Sciences logo are registered trademarks of Sight Sciences, Inc.
All other copyrights and trademarks are owned by their respective owners.

CE
2797

