iTrack™

The first canaloplasty device for both combined and standalone MIGS

The only canaloplasty device that delivers **+100 microliters of OVD** into Schlemm's canal

The only canaloplasty device that delivers OVD via a patented **pressurized mechanism**

The only canaloplasty device designed to intubate the entire **360° of Schlemm's canal**

iTrack™

It's all about the clicks (and the pressure)

20x MORE OVD

iTRACK™ DELIVERS 20x MORE OVD THAN OMNI – IT ALSO DELIVERS OVD OVER THE ENTIRE 360° OF THE CANAL

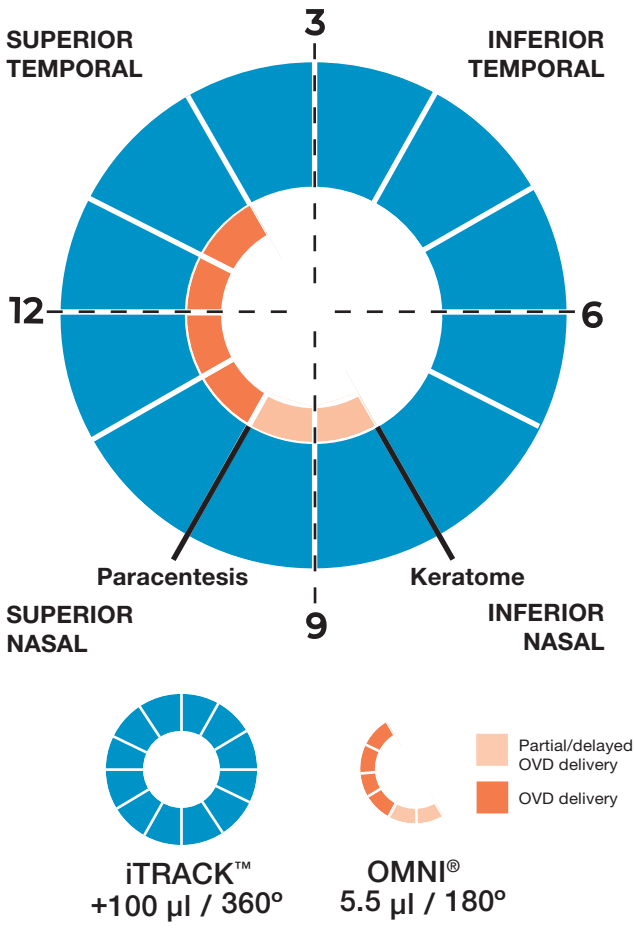
Based on an average of 3-4 clicks per clock hour, iTrack™ delivers more than 100 µl of OVD over 360° of the canal.*

OMNI® delivers 5.5 µl of OVD over 180° of the canal**

To traverse 360° of the canal, OMNI® is first intubated through 180° of the canal before it is withdrawn and removed from the goniotomy site; it is then reinserted into the goniotomy site and intubated through the remaining 180° of the canal.

iTrack™ delivers immediate, pressurized flow of OVD. Despite priming prior to the procedure, the roller mechanism of OMNI® must first be activated to ensure OVD is available at its distal tip, resulting in delayed/partial OVD delivery during the initial 1-2 seconds of viscodilation.

FIGURE 1: OVD DELIVERY INTO SCHLEMM'S CANAL (RIGHT-HANDED SURGEON)



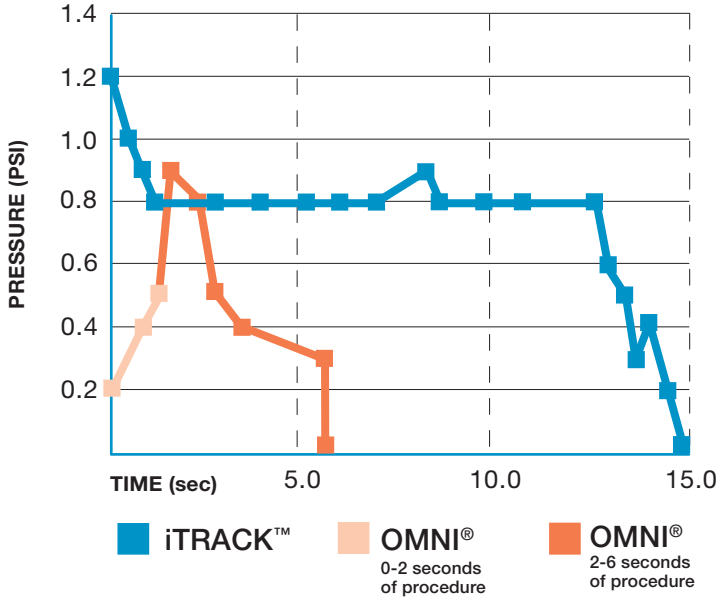
*In-house testing using a robotically controlled ViscoInjector™ with time-recording mass data to simulate the delivery of OVD over 360° of Schlemm's canal. Data available upon request.
**Based on OMNI (Model 2.0) FDA (510k) indication for use.

3x MORE PRESSURE

iTRACK™ DELIVERS OVD INTO SCHLEMM'S CANAL AT A PRESSURIZED RATE 3x GREATER THAN OMNI

iTrack™ achieves immediate, steadier and higher output pressure as compared to OMNI.+

FIGURE 2: PRESSURE (PSI) AT THE DISTAL TIP



+ In-house testing using a water column to model eye pressure, interchangeable with both the iTrack™ canaloplasty microcatheter and the OMNI surgical system, and using a transducer to measure pressure at the microcatheter tip. Data available upon request.

iTRACK™ = 360° CANALOPLASTY

iTrack™ Indication For Use: The iTrack™ canaloplasty microcatheter has been cleared for the indication of fluid infusion and aspiration during surgery, and for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open-angle glaucoma.

OMNI® = 180° CANALOPLASTY FOLLOWED BY TRABECULOTOMY

OMNI® Indication For Use: The OMNI® Surgical System has been cleared for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure (IOP) in adult patients with primary open–angle glaucoma.

	iTRACK	OMNI	
PRESSURIZED VISCODILATION	✓	✗	iTrack™ delivers OVD into the canal via a patented, pressurized mechanism (US7,967,772,B2) that is 3x greater than OMNI®.
+100 µl OVD	✓	✗	iTrack™ delivers +100 µl of OVD* over 360° of the canal. OMNI® delivers 5.5 µl of OVD over 180° of the canal.**
SURGEON-CONTROLLED	✓	✗	iTrack™ enables adjustment of OVD volume based on patient pathology. OMNI® delivers OVD via a continuous delivery mechanism and OVD volume cannot be adjusted.
360° CATHETERIZATION	✓	✗	iTrack™ is the only device that can catheterize 360° of the canal during a single intubation. OMNI® must be withdrawn and reinserted via the goniotomy site in order to intubate the remaining 180° of the canal.
ILLUMINATED FIBER OPTIC	✓	✗	The patented fiber optic tip of the iTrack™ provides continuous location feedback to prevent misdirection into the suprachoroidal space or CC ostia.
TISSUE-SPARING	✓	✗	iTrack™ preserves the angle. OMNI® removes trabecular meshwork tissue and may limit future treatment options.

INDICATIONS: The iTrack™ canaloplasty microcatheter has been cleared for the indication of fluid infusion and aspiration during surgery, and for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open-angle glaucoma.

CONTRAINDICATIONS: The iTrack™ canaloplasty microcatheter is not intended to be used for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in eyes of patients with the following conditions: neovascular glaucoma; angle closure glaucoma; and, previous surgery with resultant scarring of Schlemm's canal.

ADVERSE EVENTS: Possible adverse events with the use of the iTrack™ canaloplasty microcatheter include, but are not limited to: hyphema, elevated IOP, Descemet's membrane detachment, shallow or flat anterior chamber, hypotony, trabecular meshwork rupture, choroidal effusion, Peripheral Anterior Synechiae (PAS) and iris prolapse.

WARNINGS: The iTrack™ canaloplasty microcatheter is intended for one time use only. DO NOT re-sterilize and/or reuse, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

PRECAUTIONS: This iTrack™canaloplasty microcatheter should be used only by physicians trained in ophthalmic surgery. Knowledge of surgical techniques, proper use of the surgical instruments, and post-operative patient management are considerations essential to a successful outcome.

1. Stegmann R, Pienaar A, Miller D. Viscocanalostomy for open-angle glaucoma in black African patients. J Cataract Refract Surg. 1999;25(3):316-322.
2. Grieshaber MC, Pienaar A, Olivier J, Stegmann R. Clinical evaluation of the aqueous outflow system in primary open-angle glaucoma for canaloplasty. Invest Ophthalmol Vis Sci. 2010;51(3):1498-1504.
3. Smit BA, Johnstone MA. Effects of viscoelastic injection into Schlemm's canal in primate and human eyes: potential relevance to viscocanalostomy. Ophthalmology. 2002;109(4):786-792.
4. Docherty G, Gooi P. Canaloplasty, GATT & Trypan Blue Venography. Review of Ophthalmology. 6 Oct 2020.

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