# iTrack™

iTrack™ is the world's first canaloplasty device for both standalone and combined CE procedures— and is the only device that enables you to customize the degree of viscodilation for each patient.

**iTRACK™ = 360° CANALOPLASTY WITH PRESSURIZED VISCODILATION**
**OMNI® = 180° CANALOPLASTY FOLLOWED BY TRABECULOTOMY**

| | iTRACK | OMNI | |
|---|---|---|---|
| **PRESSURIZED VISCODILATION** | ✓ | ✗ | iTrack™ delivers OVD into Schlemm's canal via a patented, pressurized mechanism (Patent No. US7,967,772,B2). OMNI® delivers small amounts of OVD only. |
| **+100 MICROLITERS OF OVD** | ✓ | ✗ | iTrack™ delivers +100 microliters of OVD* over 360° of the canal to expand and dilate Schlemm's canal, and to improve flow through the episcleral venous system. OMNI® delivers 5.5 microliters of OVD over 180° of the canal.** |
| **SURGEON-CONTROLLED OVD DELIVERY** | ✓ | ✗ | iTrack™ enables you to adjust the OVD volume based on the patient's pathology. OMNI® delivers OVD via a continuous delivery mechanism and the OVD volume cannot be adjusted. |
| **SINGLE-PASS 360° CATHETERIZATION** | ✓ | ✗ | With a flexible design and internal guidewire, iTrack™ is the only device that can catheterize 360° of the canal during a single intubation. In contrast, OMNI® can only catheterize 180° of the canal in a single intubation; it must be withdrawn and reinserted via the goniotomy site in order to intubate the remaining 180° of the canal. |
| **ILLUMINATED FIBER OPTIC TIP** | ✓ | ✗ | The patented fiber optic tip of the iTrack™ provides continuous location feedback to prevent misdirection into the suprachoroidal space or CC ostia. OMNI® does not have a safety mechanism to safeguard against misdirection. |
| **ATRAUMATIC AND TISSUE-SPARING** | ✓ | ✗ | iTrack™ does not remove tissue and preserves the angle, thus enabling future treatments. OMNI® removes trabecular meshwork tissue and may hinder the effectiveness of future treatments. |

# iTRACK™ DELIVERS MORE OVD PER SECOND THAN OMNI® DELIVERS DURING 180° CIRCUMNAVIGATION OF SCHLEMM'S CANAL

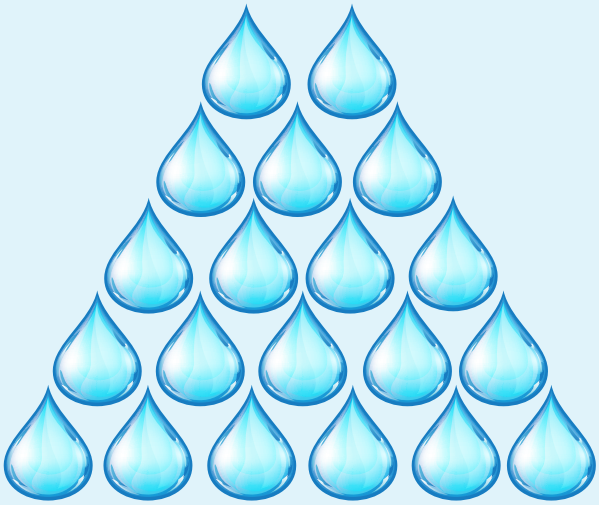
## iTrack™ delivers 10x more OVD than OMNI®

iTrack™ delivers +100 microliters of OVD over 360° of Schlemm's canal*

OMNI® delivers 5.5 microliters of OVD over 180° of Schlemm's canal**

Pressurized delivery of +100 microliters of OVD with iTrack™ improves flow through the entire conventional outflow system, including the collector channels, as observed via blanching of the episcleral veins following the iTrack™ procedure[4].

Watch the video here:
**https://youtu.be/QOkzWgGsbJw**



**iTRACK: +100 µl***

**OMNI: 5.5 µl****

## COMPARISON OF OVD DELIVERY, VOLUME:

* In-house testing (Nova Eye Medical) 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.

(1) 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.

(2) 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.



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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**glaucoma-iTrack.com**
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