



The iTrack™ canaloplasty microcatheter compared to the OMNI® device

COMPARISON OF 12-MONTH CLINICAL DATA

Combining 360° pressurized viscodilation of Schlemm’s canal with microcatheterization, the iTrack™ canaloplasty microcatheter can re-establish the conventional outflow pathway in POAG patients¹⁻³ to reduce IOP to the low teens and to reduce the medication burden by more than 50%, without removing or damaging tissue.⁴

IOP REDUCTION AT 12 MONTHS

- iTrack™ is the only device cleared by the FDA (510k) for canaloplasty, during which all potential sites of resistance in the conventional outflow pathway, including CC ostia, are addressed.
- Thus iTrack™ can comprehensively reduce both IOP and medication burden.

	DISEASE SEVERITY	ANALYSIS	N	MEAN IOP		
				BASELINE	POST-OP	% REDUCTION
iTRACK ⁴	Mild (28)	All Eyes	75	20.4 mmHg	13.4 mmHg	34%
	Moderate (12)	Combined CE	34	19.4 mmHg	13.0 mmHg	33%
	Severe (29)	Standalone	41	21.2 mmHg	13.7 mmHg	36%
	Unavailable (6)					
OMNI ⁵	Not reported	Standalone, Baseline IOP > 18 mmHg	24	21.8 mmHg	15.6 mmHg	28%
		Standalone, Baseline IOP < 18 mmHg	24	15.4 mmHg	13.9 mmHg	9%

MEDICATION REDUCTION AT 12 MONTHS

DISEASE SEVERITY	ANALYSIS	N	MEAN IOP			
			BASELINE	POST-OP	% REDUCTION	
iTRACK⁴	Mild (28)	All Eyes	75	2.8	1.1	61%
	Moderate (12)	Combined CE	34	2.6	0.9	65%
	Severe (29)	Standalone	41	3.2	1.4	56%
	Unavailable (6)					
OMNI⁵	Not reported	Standalone, Baseline IOP > 18 mmHg	24	1.7	1.2	29%
		Standalone, Baseline IOP < 18 mmHg	24	2.0	1.3	35%

COMPLICATIONS/ADVERSE EVENTS

- iTrack™ is a tissue-sparing, implant-free MIGS procedure with no physiological changes.
- iTrack™ offers an excellent safety profile and eliminates many of the complications seen with other MIGS, such as stent malposition and PAS.^{6,7}
- As an added benefit, iTrack™ also minimizes ECL.⁸⁻¹⁰

iTRACK⁴ Intraoperative bleeding at gonio site (n not specified)
Transient postoperative microhyphema (n not specified)

OMNI⁵ Mild AC inflammation, 6 (12.5%)
Posterior capsule opacity, 5 (10.4%)
IOP increase ≥ 10 mmHg above baseline > 30 days postoperative, 3 (6.3%)
Cystoid maculae edema, 3 (6.3%)
Corneal edema, 2 (4.2%)
Hyphema > 1mm, 2 (4.2%)

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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 Synchia (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. Viscoanalastomy 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 viscoanalastomy. Ophthalmology. 2002;109(4):786-792.
4. Gallardo MJ, Supnet RA, Ahmed IK. Viscodilation of Schlemm's canal for the reduction of IOP via an ab-interno approach. Clinical Ophthalmology, Vol 12, August 2018. https://doi.org/10.2147/OPTH.S177587.
5. Vold SD, Williamson BK, Hirsch L, Aminlari AE, Cho AS, Nelson G, Dickerson JE. Canaloplasty and Trabeculotomy with the OMNI System in Pseudophakic Patients with Open-Angle Glaucoma: the ROMEQ Study. OPHTHALMOLOGY GLAUCOMA (2020)
6. Popovic M, Campos-Moller X, Sahab H, Ahmed IK. Efficacy and Adverse Event Profile of the iStent and iStent Inject Trabecular Micro-bypass for Open-angle Glaucoma: A Meta-analysis. J Clin Glaucoma Pract 2018;12(2):67-84.
7. ElMallah MK, Seibold UK, Kahook MY et al. 12-Month Retrospective Comparison of Kahook Dual Blade Excisional Goniotomy with iStent Trabecular Bypass Device Implantation in Glaucomatous Eyes at the Time of Cataract Surgery. Adv Ther 36, 2515-2527 (2019).
8. Lubeck DM, Noveck RJ. Evaluation of Endothelial Cell Density and Loss Following iTrack Ab-Interno Canal Based Surgery. ICGS 2020 (Paper Presentation, P060).
9. Lubeck DM, Noveck RJ. Evaluation of endothelial cell density and loss following iTrack ab-interno canal based surgery. ESCRS 2020 (Paper Presentation).
10. Lubeck DM, Singh IP, Noveck RJ. Evaluation of Endothelial Cell Density and Loss Following iTrack Ab-Interno Canal Based Surgery. ASCRS 2020 (Paper Presentation).

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