ellex

iTrack™

A restorative approach to glaucoma

ABIC™ (AB-INTERNO CANALOPLASTY)

CANALOPLASTY

Helping the world see clearly

The next step in canal-based glaucoma surgery

With the iTrack™ surgical system from Ellex, you can restore the eye's natural outflow pathway to reduce intraocular pressure (IOP) and eliminate or reduce the medication burden — naturally, safely, and efficaciously. It's a minimally invasive approach that enables you to intervene earlier, and all whilst maximizing patient quality of life.

Behind the apparent simplicity of ABiC™ — ab-interno canaloplasty — and Canaloplasty is the proprietary iTrack™ surgical system, which has been intelligently designed and meticulously tested across each treatment stage.

A range of glaucoma treatment options

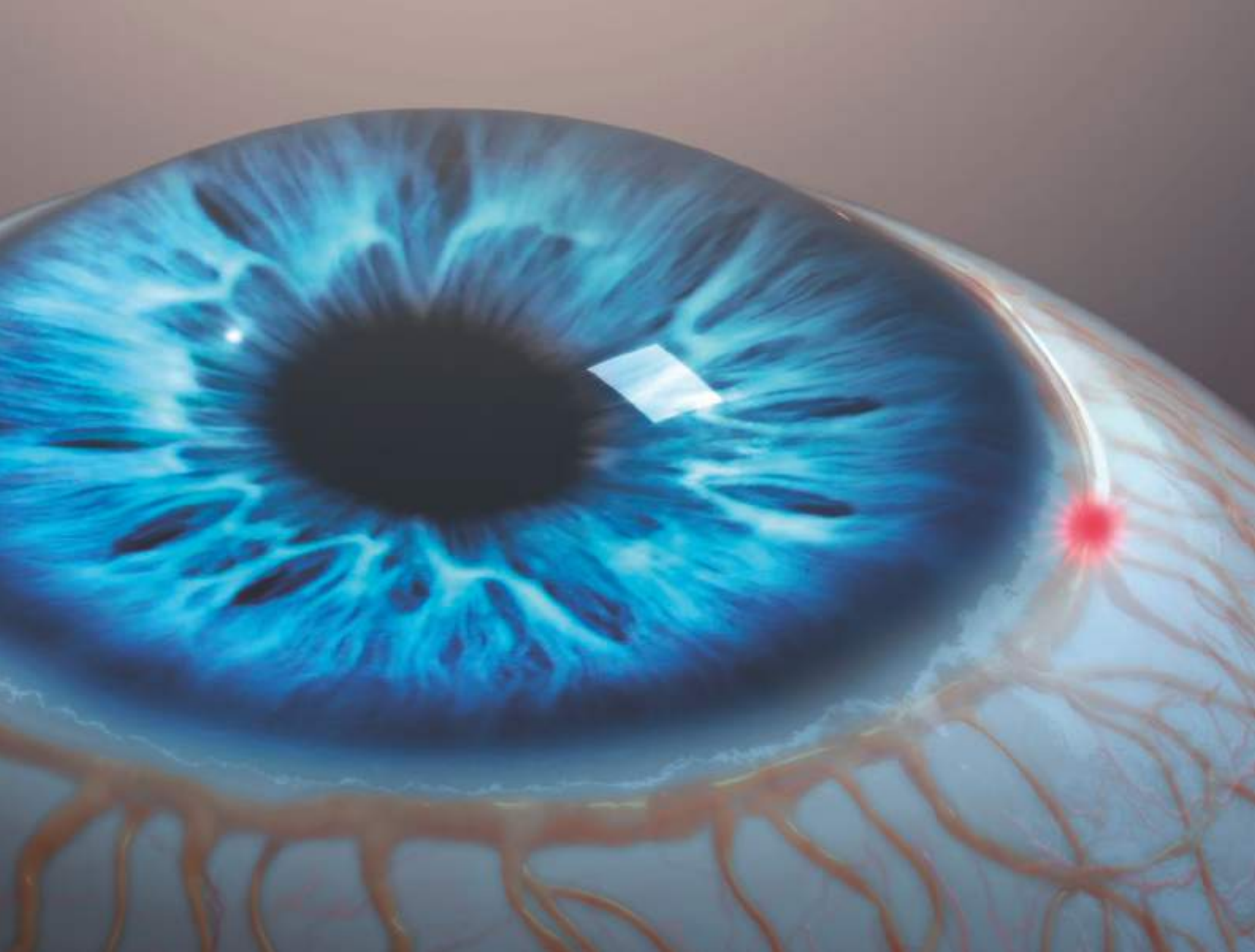
Choose iTrack™, and you can select from two treatment modalities, which comprise:

ABIC™ — AB INTERNO CANALOPLASTY

CANALOPLASTY

ABiC™ is a comprehensive minimally invasive, canal-based glaucoma surgery performed with the iTrack™ surgical system that flushes out the natural outflow channels without damaging tissue, and without leaving behind a stent or shunt.

For patients with later stage disease, Canaloplasty performed with the iTrack™ surgical system is a proven and effective solution that means patients avoid the risks and discomfort associated with trabeculectomy.



iTrack™ surgical system — minimally invasive, maximally effective

The iTrack™ surgical system, which comprises the iTrack™ microcatheter, the ViscoInjector™ viscoelastic injector, and the iLumin™ illumination source, is a crucial element in the success of ABiC™ and Canaloplasty.

Unique illumination

Featuring a unique, proprietary illuminated tip, you can monitor progress of the iTrack™ microcatheter through every procedural step. iTrack's tip is also lubricious and atraumatic, which means that ease of insertion is enhanced, and direction accuracy is maximized to prevent the catheter broaching the collector channel ostia.

Intelligent navigation

An internal guide wire within iTrack™ provides excellent tactile feedback as the tip is advanced, offering a vital insight on whether the canal is tight, grainy, or completely open.

Precise viscodilation

The ViscoInjector™, which attaches to the iTrack™ microcatheter, is manually operated using a tactile and audible knob to release a precisely measured aliquot of viscoelastic per click.

The delivery of viscoelastic during the withdrawal of iTrack™ from Schlemm's canal accomplishes a vital additional function that complements the mechanical opening achieved with the iTrack™ microcatheter; it separates the compressed tissue planes of the trabecular meshwork, causing any herniated inner wall tissue to withdraw from the collector channels*.

*Data on file. Ellex Medical.


iTrack SURGICAL SYSTEM™
Polymer shaft and distal atraumatic tip
Optical fiber, light transmission
Lumen
Internal guide wire
Illuminated fiber optic tip provides continuous location feedback, eliminating misdirection into a suprachoroidal drainage system or the collector channel ostia.
Internal guide wire enables you to push through herniations and to maneuver through tight areas or structures of the canal, without the risk of creating an artificial pathway.

ABiC™: adjunctive, restorative — and comprehensive

ABiC™ performed using Ellex's iTrack™ surgical system comprehensively and successfully addresses all aspects of potential outflow resistance. It's a minimally invasive glaucoma surgery that allows you to lower IOP and/or reduce the patient medication burden, both in cases of controlled and uncontrolled glaucoma — maximizing efficacy and minimizing tissue trauma.

Safety – and efficacy

Not only does ABiC™ deliver on the MIGS promise of safety, but it is also effective.

On average, ABiC™ achieves a reduction in mean IOP of 30%, combined with a 50% reduction in medication dependence[1]. (Refer to Table 1.)

During the procedure, 360° viscodilation of Schlemm's canal with the iTrack™ microcatheter means that you can pop open herniations to open up the ostia of the collector channels and re-establish outflow.

Removing the guesswork

The most defining aspect of ABiC™ is its comprehensive approach. Unlike stent-based MIGS, where only a segment of Schlemm's canal is addressed, or where the trabecular meshwork is targeted in isolation, ABiC™ with iTrack™ addresses all aspects of the outflow pathway, eliminating the risk that the blockage area will be missed or sub-optimally treated.

Adjunctive treatment

ABiC™ performed with the iTrack™ surgical system can also be used in conjunction with other MIGS devices or treatments — and, as an atraumatic procedure, it does not preclude future treatment options.

Seamless pairing with SLT

ABiC™ can be deployed synergistically with Selective Light Therapy (SLT) to control IOP by restoring the natural outflow pathways. SLT stimulates cellular regeneration to create a healthier, more porous TM structure and acts to expand Schlemm's canal, offering a complementary action mechanism to ABiC™.

Table 1: ABiC Case Series - 12 Month Results[1]

	ABiC with Cataract Surgery			Standalone ABiC		
Exam	**n**	**Mean IOP (mm Hg) ± SD**	**Mean Medications (n) ± SD**	**n**	**Mean IOP (mm Hg) ± SD**	**Mean Medications (n) ± SD**
Baseline	130	17.1 ± 5.0	20 ± 1.0	98	21.5 ± 7.4	3.0 ± 1.0
3 Months	92	13.5 ± 3.1	0.0 ± 1.0	65	16.4 ± 4.3	1.0 ± 1.0
6 Months	83	14.0 ± 3.6	0.0 ± 1.0	51	15.5 ± 3.9	1.0 ± 1.0
12 Months	34	13.1 ± 2.1	1.0 ± 1.0	14	13.6 ± 1.9	1.0 ± 1.0

[1] 228-eye ABiC 12-Month Case Series Data, presented at ASCRS 2016. Data on file. Ellex Medical.

Canaloplasty: less complications, excellent efficacy

With over 70,000 procedures performed to date, clinical studies show that Canaloplasty performed using Ellex's iTrack™ surgical system has an excellent safety profile, with minimal post-operative follow-up, faster recovery times, and infrequent intra-operative and post-operative complications[1,2,3].

Precisely restorative

Canaloplasty works by restoring the eye's natural outflow pathways. During the procedure, 360° viscodilation of Schlemm's canal opens up the ostia of the collector channels and re-establishes outflow. Additionally, the creation of the scleral lake, Descemet's window and a tensioning suture help to contribute to a sustained reduction in IOP.

Blebless glaucoma surgery

Canaloplasty is a non-penetrating surgery that does not require the creation of a permanent hole in the eye that can result in bleb formation, and its deployment doesn't preclude or affect the outcome of any future surgical intervention.

A comprehensive approach

By addressing all possible resistance sites, including potentially occluded collector channels, Canaloplasty delivers post-operative pressures in the range of 12-14 mmHg, similar to that achieved with trabeculectomy — but with fewer complications and an improved safety profile[1,3]. (Refer to Table 3.)

In a three-year multi-center trial by Lewis et al, Canaloplasty achieved significantly lower IOP and dependence on medications. When performed in conjunction with cataract surgery, Canaloplasty resulted in a 42% reduction in mean IOP from 23.5 mmHg to 13.6 mmHg, combined with an 80% reduction in medication use[1]. (Refer to Table 2.)

Table 2: Canaloplasty Multi-Center Trial — Three Year Results[1]

	Canaloplasty		
Exam	**n**	**Mean IOP (mm Hg) ± SD**	**Mean Medications (n) ± SD**
Baseline	103	23.5 ± 4.5	1.9 ± 0.8
6 Months	86	16.1 ± 3.4	0.4 ± 0.7
12 Months	91	16.1 ± 3.9	0.6 ± 0.8
24 Months	89	16.1 ± 4.0	0.6 ± 0.8
36 Months	89	16.1 ± 3.5	0.6 ± 0.9

Table 3: Comparison — Complication Rates

	Canaloplasty[1]	**Trabeculectomy (TvT)[4]**	**Tube Shunts (TvT)[4]**
Number of Patients	157	107	105
Reoperation for Complications	5 (3.2%)	9 (9%)	15 (14%)
Vision Loss of ≥ 2 Snellen Lines	0 (0%)	23 (22%)	17 (16%)
Serious Complications	1 (0.6%)	28 (27%)	24 (22%)

[1] *Lewis RA, von Wolff K, Tetz M, et al. Canaloplasty: three-year results of circumferential viscodilation and tensioning of Schlemm's canal using a microcatheter to treat open-angle glaucoma. J Cataract Refract. Surg. 2011(37):682-690.*

[2] *Bull H, von Wolff K, Korger N, Tetz M. Three-year canaloplasty outcomes for the treatment of open-angle glaucoma: European study results. Graefes Arch Clin Exp Ophthalmol. 2011;249:1537-1545.*

[3] *Brüggemann A, Despouy JT, Wegent A, Müller M. Intraindividual comparison of Canaloplasty versus trabeculectomy with mitomycin C in a single-surgeon series. J Glaucoma. 2013;22(7):577-583*

[4] *Gedde, SJ et al Review of the results from the Tube vs. Trabeculectomy Study Current Opinion in Ophthalmology 2010, 21:123-128.*

What physicians are saying about Ellex iTrack™

"I have been a practicing glaucoma specialist for over 10 years. The introduction of ABiC has completely changed my glaucoma treatment paradigm. Not only has ABiC proven itself to be highly effective in lowering IOP and reducing medication dependence, it also offers an excellent safety profile. There is no manipulation of the conjunctiva, and the post-op recovery resembles that of cataract surgery."

MAHMOUD A. KHAIMI, MD
USA

"Rather than trying to mechanically change or bypass the pathway of aqueous outflow, ABiC and Canaloplasty act to restore the natural outflow process by targeting all aspects of the outflow system; that is, the trabecular meshwork, Schlemm's canal, and the collector channels. This is an important distinction of these procedures — especially considering that it is not always understood where the point of maximum resistance lies. It therefore makes sense to apply a procedure that comprehensively addresses the entire outflow system."

MARK J. GALLARDO, MD
USA

"While various MIGS devices may work on specific sections of the outflow system, the multiple mechanisms of ABiC let us hedge our bets and, in my opinion, have a better chance of getting that reduction of pressure in the right type of patient population."

PAUL I. SINGH, MD
USA

iTrack™

Find out how the iTrack™ surgical system will help you restore the eye's outflow pathways in the treatment of glaucoma — naturally, safely, and efficaciously.

Contact us now to schedule a demonstration

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Helping the world see clearly

Ellex is the manufacturer of the iTrack™ Canaloplasty microcatheter for the reduction of intraocular pressure (IOP) in adult patients with open-angle glaucoma. It has been approved for the indication of fluid infusion and aspiration during surgery, and for catheterization and viscodilation of Schlemm's canal during the Canaloplasty procedure. Ellex does not accept any responsibility for use of the iTrack™ Canaloplasty microcatheter outside of these indications.

iTrack™ has a CE Mark (Conformité Européenne) and US Food and Drug Administration (FDA) 510(k) # K080067 for the treatment of open-angle glaucoma.

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