



Nova Eye Medical Launches Next Generation Canaloplasty Device for Glaucoma, *iTrack™ Advance*

California, USA, 19 April 2022 – Nova Eye Medical Limited (ASX: EYE) (Nova Eye Medical or the Company), a medical technology company committed to advanced ophthalmic treatment technologies and devices, today announces the launch of its next generation canaloplasty device, *iTrack™ Advance*, in select markets in Europe and the Asia Pacific.

The *iTrack™ Advance* builds on the legacy of the Company's proprietary *iTrack™* device. Launched in 2008, the *iTrack™* device has been used in more than 100,000 canaloplasty procedures globally.

Pioneered by Nova Eye Medical (originally *iScience Interventional, Inc.*), canaloplasty is a surgical treatment for glaucoma that is designed to re-establish the function of the conventional outflow pathway, the primary drainage pathway in the eye responsible for regulating the outflow of aqueous fluid. This contrasts with traditional glaucoma surgical treatments that bypass or remove a portion of the conventional outflow pathway.

According to Managing Director of Nova Eye Medical, Tom Spurling, there has been a marked increase in interest in canaloplasty from both surgeons and the wider industry over the past 12-18 months.

“An implant-free procedure that preserves the trabecular meshwork for subsequent procedures, canaloplasty offers significant utility to surgeons and their patients. The introduction of the *iTrack Advance™* underscores our commitment to grow the canaloplasty field.”

“As more companies enter the field it will bring more mass and more interest into the marketplace, which will undoubtedly foster further growth. With our strong IP portfolio and industry-leading features, we are well positioned to capitalize on this growth.”



The *iTrack™ Advance* features the proprietary illuminated fiber optic tip of the original *iTrack™* device, which allows the surgeon to continuously monitor the location of the device in Schlemm's canal. It also features a proprietary guide-wire mechanism that enables the microcatheter to catheterize up to 360 degrees of the canal in a single intubation.

The new *iTrack™ Advance* device is designed to improve the overall efficiency of the canaloplasty procedure.

The Company expects the introduction of *iTrack™ Advance* to drive increased surgeon uptake of the canaloplasty procedure by cataract surgeons and comprehensive ophthalmologists. To date, the original *iTrack™* device has been used almost exclusively by glaucoma surgeons.

“Canaloplasty is globally recognized as a highly effective treatment option for glaucoma. The intricacies of the procedure, however, which have included manual intubation of the microcatheter through the canal using forceps, previously limited its adoption by a broad cross section of surgeons.”

“With *iTrack™ Advance* we have taken the clinically proven *iTrack™* microcatheter and engineered it into an intuitive, easy-to-use handpiece. It's the perfect marriage of clinical excellence and surgical efficiency,” commented Mr. Spurling.

“We see *iTrack™ Advance* being readily adopted into the glaucoma toolkit of cataract surgeons and comprehensive ophthalmologists. This will ensure improved access to the canaloplasty procedure for a greater number of glaucoma patients worldwide,” added Mr. Spurling.

Over the coming months the Company will solidify its position for canaloplasty in Europe and support the market roll-out of the new *iTrack™ Advance* via a series of market development and clinical development initiatives, including a surgical training program in Germany.

“Canaloplasty has a rich history in Germany. It was formally recognized in 2014 as the new ‘gold standard’ in the surgical treatment of glaucoma by the patient advocacy group



German Federate Eye Association. In 2020 we established a direct commercial team and a wholly owned subsidiary in Germany to support future growth of the canaloplasty market. We are currently ramping up our local German infrastructure to support the launch of the *iTrack™ Advance*,” said Mr. Spurling.

The Company will showcase the *iTrack™ Advance* (not for sale or use in the USA) to surgeons from outside the USA during the 2022 annual meeting of the American Society of Cataract and Refractive Surgery (ASCRS), 22-26 April in Washington DC.

For more information about *iTrack Advance™*, including important safety information, visit <http://iTrack-Advance.com>

ABOUT NOVA EYE MEDICAL

Nova Eye Medical Limited is a medical technology company that develops, manufactures and sells a portfolio of proprietary ophthalmic treatment technologies and devices. Used by eye surgeons in more than 100 countries globally, these technologies include the *iTrack™* portfolio of canaloplasty devices for the treatment of glaucoma. The Company also manufactures and sells the proprietary Molteno3® glaucoma drainage device for the treatment of severe or complex glaucoma. With its sales headquarters based in Fremont, California, Nova Eye Medical is supported by sales offices in Adelaide, Australia and Berlin, Germany, and a global network of more than 50 distribution partners. Manufacturing facilities are located in Fremont, California and Dunedin, New Zealand.

For additional information about Nova Eye Medical and its technologies, please visit: www.nova-eye.com

ABOUT CANALOPLASTY

First introduced in 2008, canaloplasty is a surgical treatment for glaucoma that targets the main sites of outflow resistance in the conventional outflow pathway: the trabecular meshwork, Schlemm’s canal, and the distal collector channels. Based on the same



principles as angioplasty, a flexible microcatheter is cannulated 360 degrees around Schlemm's canal during the procedure to manually break and remove blockages. Next, viscoelastic fluid is injected into Schlemm's canal as the microcatheter is withdrawn to dilate the distal outflow system and to improve the function of the trabecular meshwork.

Canaloplasty is typically performed using either of the following two surgical techniques:

- Performed via an ab-interno surgical technique, canaloplasty is a highly effective treatment option for cases of mild-moderate glaucoma. It typically reduces intraocular pressure (IOP) to the low teens. It has also been observed to reduce patient dependence on medications. Importantly, the ab-interno surgical technique is an implant-free, tissue-sparing procedure that preserves future treatment options.
- Performed via an ab-externo surgical technique, canaloplasty is a highly effective treatment option for patients with severe glaucoma that overcomes the risks and discomfort associated with traditional glaucoma surgery. With over 100,000 procedures performed to date, clinical studies show that canaloplasty has an excellent safety profile, with minimal post-operative follow-up, fast recovery time, and infrequent intra-operative and postoperative complications.

ABOUT THE ITRACK™ PORTFOLIO

Nova Eye Medical (formerly iScience Interventional) pioneered the canaloplasty market with the launch of the world's first canaloplasty device, *iTrack*™, in 2008. Since then, more than 100,000 canaloplasty procedures have been performed with the *iTrack*™ device, cementing its role in the treatment of glaucoma both as a standalone procedure and in combination with cataract surgery. Launched in 2022, the *iTrack*™ *Advance* leverages the proprietary features of the original *iTrack*™ device but incorporates a new handheld injector and custom-designed cannula.



iTrack™ Advance has a CE Mark (Conformité Européenne) for the treatment of open-angle glaucoma and is currently available in selected markets in Europe and the Asia Pacific. iTrack™ Advance is not available for use or sale in the USA. The iTrack™ Advance is indicated for 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.

iTrack™ has a CE Mark (Conformité Européenne) and US Food and Drug Administration (FDA) 510(k) # K080067 for the treatment of open-angle glaucoma. 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. The iTrack™ canaloplasty microcatheter is currently not 510(k) cleared for use with the ab-interno technique in the United States.

For additional information about the iTrack™ portfolio, including safety information, please visit: <https://nova-eye.com>
