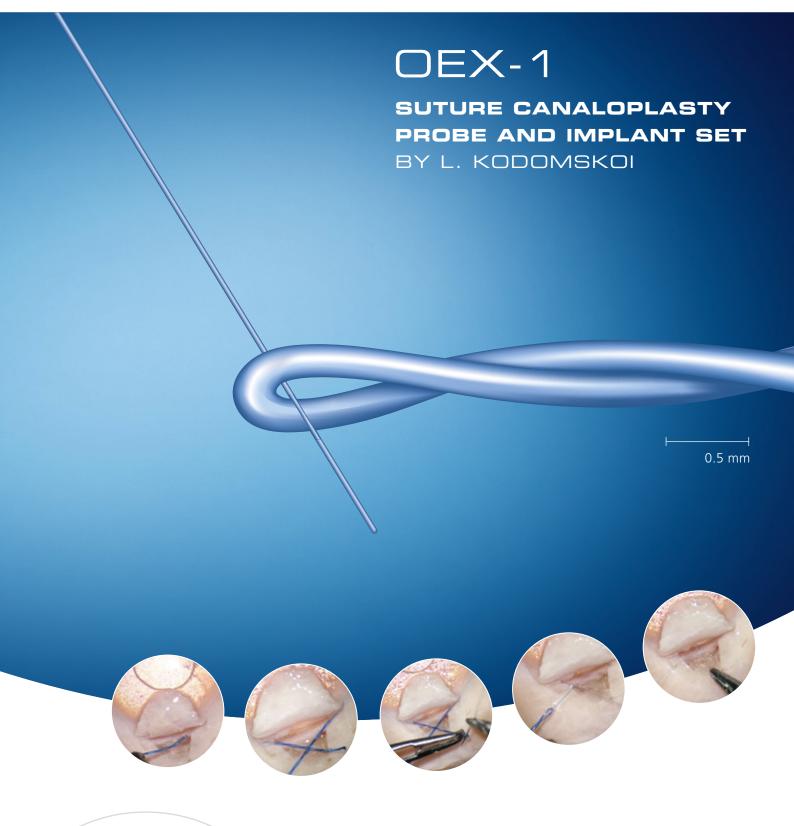
# onate Com





FOR OPEN-ANGLE GLAUCOMA

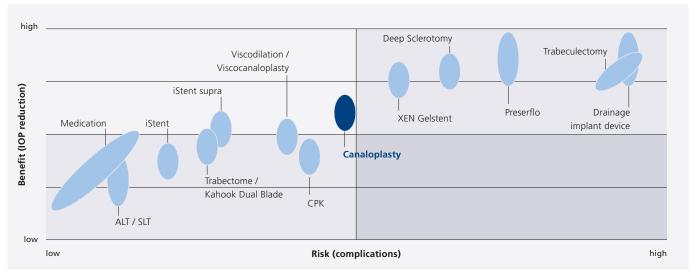


## OEX-1

ALL-IN-ONE GLAUCOMA SOLUTION
FOR AB-EXTERNO SUTURE-PROBE CANALOPLASTY

#### **IDEAL RISK-BENEFIT RATIO**

The rising number of glaucoma surgeries worldwide has encouraged various innovations, such as minimally-invasive stent solutions (MIGS) for faster and safer surgeries. While MIGS procedures reduce the incidence of complications, they are not very effective at lowering the IOP. Whereas trabeculectomy, the classic filtering technique, can lower the IOP immensely, it carries a high risk for complications or adverse effects. High IOP reduction with high risk may be the only option for some patients, but for a large proportion, a medium IOP reduction with **significantly lower risk** is the better choice.

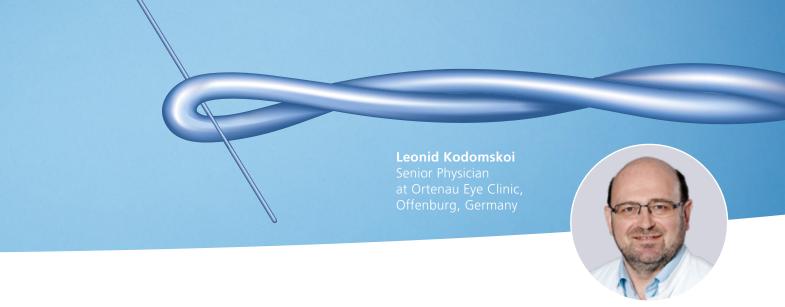


**Source:** Hoffmann, E. M., Hengerer, F., Klabe, K., Schargus, M., Thieme, H., & Voykov, B. (2021). Aktuelle Glaukomchirurgie. Der Ophthalmologe, 118(3), 239-247.



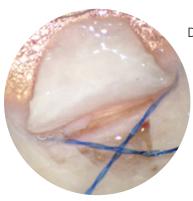
In comparison to other techniques for IOP reduction, **canaloplasty** has an **ideal risk-benefit ratio**. It is an established surgical procedure to improve the **natural outflow** in open-angle glaucoma and thereby reducing the intraocular pressure. It has **permanently effective outcomes** while showing a low risk for complications intra- and postoperatively.

In the past years, canaloplasty was mainly performed with micro-catheter devices. Although showing good results, these micro-catheter devices have one major disadvantage: high cost per case.



#### **EFFECTIVE AND ECONOMICAL SOLUTION**

In search of a better balance between effectiveness, complications and costs, Leonid Kodomskoi (Offenburg, Germany) has developed an innovative yet economic alternative: The Onatec OEX-1 twisted 6-0 suture probe with atraumatic edges and a monofilament 10-0 suture implant.



During this simple and effective procedure, a deep scleral flap with detached Schwalbe's line needs to be prepared in order to insert the 6-0 suture probe into the Schlemm's canal. After a 360° catheterization, a 10-0 monofilament polypropylene suture is tied to the eyelet of the twisted probe and inserted into the Schlemm's canal by retracting the suture-probe 360° backwards. The 10-0 suture implant remains inside the Schlemm's canal to improve long-term stability of the IOP reduction.

In comparison to other micro-catheter devices, the major advantage of the **OEX-1** glaucoma solution is the **lower cost per case**.

#### ADVANTAGES OF OEX-1 AT A GLANCE:

- Usable for canaloplasty and trabeculotomy (GATT)
- Safe and permanent widening of Schlemm's canal
- 44 % or 10.2 mmHg IOP reduction from baseline after 12 months
- 16 % lower IOP compared to competitor products after 12 months
- 58 % of the patients obtained an IOP
   15 mmHg after 12 months

- 78 % of the patients obtained an IOP<18 mmHg after 12 months</li>
- Tissue-protecting due to atraumatic probe tip design
- Spiral structure of suture probe enables intraoperative assessment of function and condition of the venous collectors
- Easy and reliable fixation of the implant



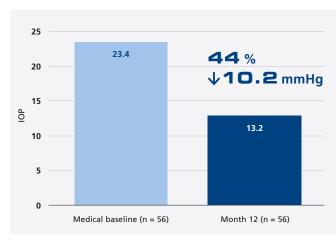
## OEX-1

ALL-IN-ONE GLAUCOMA SOLUTION
FOR AB-EXTERNO SUTURE-PROBE CANALOPLASTY

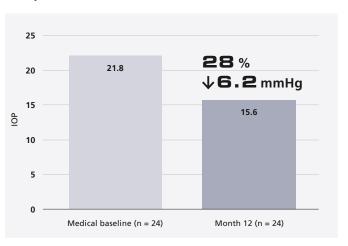
#### **MEAN IOP REDUCTION OF 44%**

In comparison to competitors, the OEX-1 solution is capable of reducing the mean IOP by up to 10.2 mmHg (44 %) postoperatively after one year.

#### OEX-1



#### Competitor



IOP reduction after 1 year: OEX-1 vs. competitor

Source OEX-1: https://www.dgii.org/uploads/jahresband/2013/055\_Kodomski.pdf

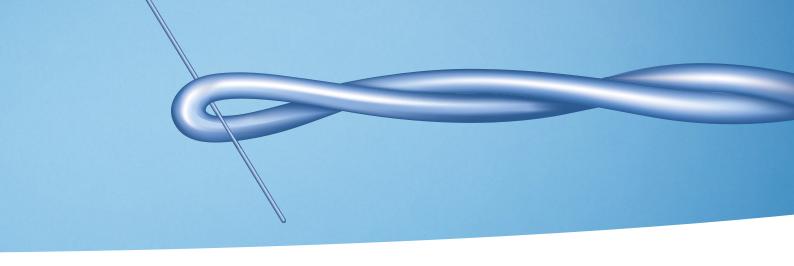
**Source Competitor:** Vold SD, Williamson BK, Hirsch L, Aminlari AE, Cho AS, Nelson C, Dickerson JE Jr. Canaloplasty and Trabeculotomy with the OMNI System in Pseudophakic Patients with Open-Angle Glaucoma: The ROMEO Study. Ophthalmol Glaucoma. 2021;4:173-181. doi: 10.1016/j.ogla.2020.10.001.

### Postoperative results show, that the OEX-1 is lowering the IOP and medication while preserving the visual acuity.

	Preoperative (n = 56)	Postoperative (n = 56)
Visual acuity (VA)	0.63 ± 0.24	0.63 ± 0.23
IOP mean (mmHg)	23.4 ± 6.39	13.2 ± 3.71
Local medication (substances)	2.5 ± 0.97	0.07 ± 0.32

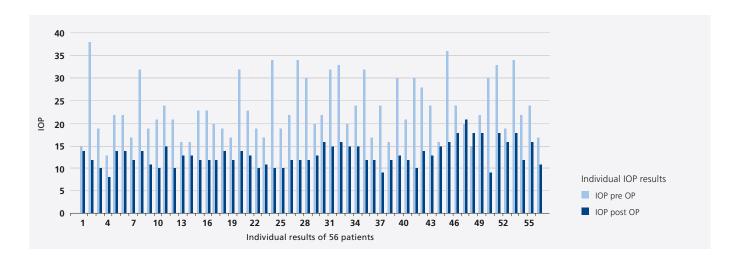
General IOP lowering results (Ø 23.4 mmHg preoperativ vs. Ø 13.2 mmHg after one year.

 $\textbf{Source:} \ https://www.dgii.org/uploads/jahresband/2013/055\_Kodomski.pdf$ 



### EXCEPTIONAL RESULTS AND LOW COMPLICATION RATE

The individual 1-year results of this procedure show that the IOP was below 18 mmHg in 78 % of all patients, without additional medication. The majority of patients (58 %) achieved an exceptional result of IOP below 15 mmHg, without additional medication or surgeries. In average, the IOP was reduced by 10 mmHg over 12 months.



The complication rate of OEX-1 is similar to the results achieved in canaloplasty using a microcatheter. Therefore the use of the suture-probe is a safe and sufficient alternative to other solutions.

Complications / Course	n (%)
Gross hyphema (> 1 mm)	1 (2.0)
Microhyphema (< 1 mm)	2 (4.0)
Bleb leakage / bleb repairing suture	1 (2.0)
Hypotony (< 5 mmHg)	0 (0.0)
Choroidal detachment	0 (0.0)

n (%)
9 (18.0)
2 (4.0)
2 (4.0)
2 (4.0)

n indicates number of cases absolute and relative to the number of controlled eyes (n = 50); Nd:YAG, neodymium-doped yttrium aluminium garnet.

**Sources:** Kodomskoi L, Kotliar K, Schröder AC, Weiss M, Hille K. Suture-Probe Canaloplasty as an Alternative to Canaloplasty Using the iTrack Microcatheter. J Glaucoma. 2019 Sep;28(9):811-817. doi: 10.1097/IJG.000000000001321. PMID: 31283701.

"Fadensondenkanaloplastik: 1-Jahres-Ergebnisse und eine Erfolgsfaktorenanalyse" - L. Kodomskoi, A. C. Schröder, K. Hille https://www.dgii.org/uploads/jahresband/2013/055\_Kodomski.pdf



ONALENE® POLYPROPYLENE (PP) MONOFILAMENT G-OEX1

**CANALOPLASTY SUTURE SET BY ONATEC** 

6/0, 8 cm suture probe and 10/0, 16 cm suture implant



#### OPENING THE CONJUCTIVA

G-19750 WESTCOTT

**SCISSORS** 

blunt tips, curved, standard blades



Danador

#### MARKING OF THE SCLERAL FLAP 2.

G-32209 TOBIAS NEUHANN

SCLERAL FLAP MARKER

5.0 mm and 4.0 mm, U-shaped marking patterns swivel handle allows marking from temporal or superior approach





#### 3a. INITIAL INCISION (SINGLE-USE)

G-34026 NANOEDGE PARACENTESIS KNIFE

15°, straight, 6 pcs. per box, sterile



#### 3b. INITIAL INCISION (REUSABLE)

G-31487 **DIAMOND KNIFE** 

for viscocanalostomy, 0.5 mm wide, 70° diamond blade width 0.5 mm, length 4.0 mm, thickness 0.2 mm



#### 4a. FLAP DISSECTION (SINGLE-USE)

G-34081 NANOEDGE CRESCENT KNIFE

> angled, bevel up, 2.0 mm 6 pcs. per box, sterile





#### 4b. FLAP DISSECTION (REUSABLE)

G-14105 MICRO ROUND KNIFE

for viscocanalostomy

0.8 mm diameter disc-shaped blade





**DIACLEAN DIAMOND CRESCENT KNIFE, 2.0 MM** G-38466

round spatula shape, 40° angled, titanium handle width 2.0 mm, length 4.0 mm, thickness 0.2 mm





### OPTIONAL ACCESSORIES

#### 5. CONJUCTIVA FORCEPS

G-18783 DRESSING FORCEPS

serrated jaws 1.2 mm

**G-18810** *DRAEGER* 

**CONJUNCTIVA FORCEPS** 

1.2 mm wide

2 atraumatic fixation knobs







#### 6. TRABECULUM SCISSORS (VANNAS)

G-19745 TRABECULUM SCISSORS

sharp tips, straight, 8.5 mm blades

1.5 mm pivot width



#### 7. COLIBRI FORCEPS

G-18960 MICRO COLIBRI FORCEPS

delicate, 1 x 2 teeth, 0.12 mm 5 mm tying platform





#### 8. TYING FORCEPS

G-19032 TYING FORCEPS

angled, 7.5 mm 6 mm tying platform





#### 9. DELICATE NEEDLE HOLDER

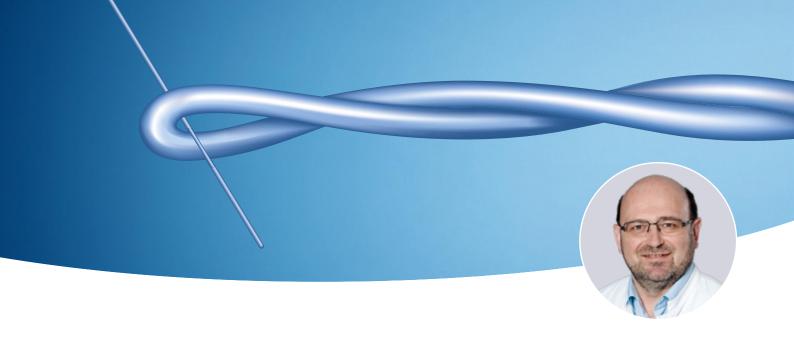
**G-17500** BARRAQUER

NEEDLE HOLDER

10 mm delicate jaws, curved, without lock

0.8 x 0.55 mm tip





#### STEP BY STEP

## THE APPLICATION OF OEX-1 IS FOLLOWING THE PRINCIPLES OF CANALOPLASTY WITHOUT VISCODILATION.



- Deep sclerotomy as standard access to the Schlemm's canal.
- 1b Deep scleral flap (4x4 mm) down to 50 µm of choroid.



Safe fixation of 10-0 implant suture in eyelet of twisted 6-0 suture probe and 360° retraction of probe so the implant remains inside the Schlemm's canal.



- **2a** Widening ostia of Schlemm's canal with viscoelastic.
- **2b** Inserting 6-0 suture probe.



- Setting optimum tension on trabecular meshwork and knotting the implant suture.
  - ⇒ Permanent widening of Schlemm's canal



Suture probe exit at corresponding ostium of Schlemm's canal after 360° catheterization.
Intraoperative assessment of function and condition of the venous collectors during catheterization.



Closure of scleral flap and conjunctiva should be watertight to avoid subconjunctival filtration.

Manufacturer of Onatec suture materials:

**CÉ 2797** FSSB Chirurgische Nadeln GmbH (Jestetten, Germany) **CÉ 1639** Surgical Specialties Mexico S. de R.L. der C.V.

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Illustrations not drawn to scale (some illustrations are reduced to 60 %).

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