



CyPass[®] Micro-Stent

Unlocking the Potential of the
Suprachoroidal Space

Caution: Investigational Device. Limited by Federal (USA) law to investigational use.

Glaucoma: Major **Unmet** Clinical Need



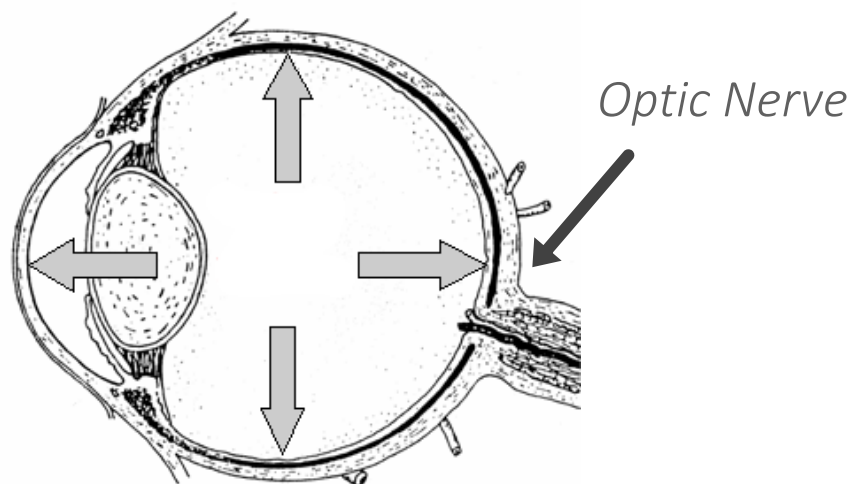
Glaucoma is one of the **top 3** ophthalmic diseases

Affects **65 million** people worldwide
(the leading cause of blindness in the developed world¹)

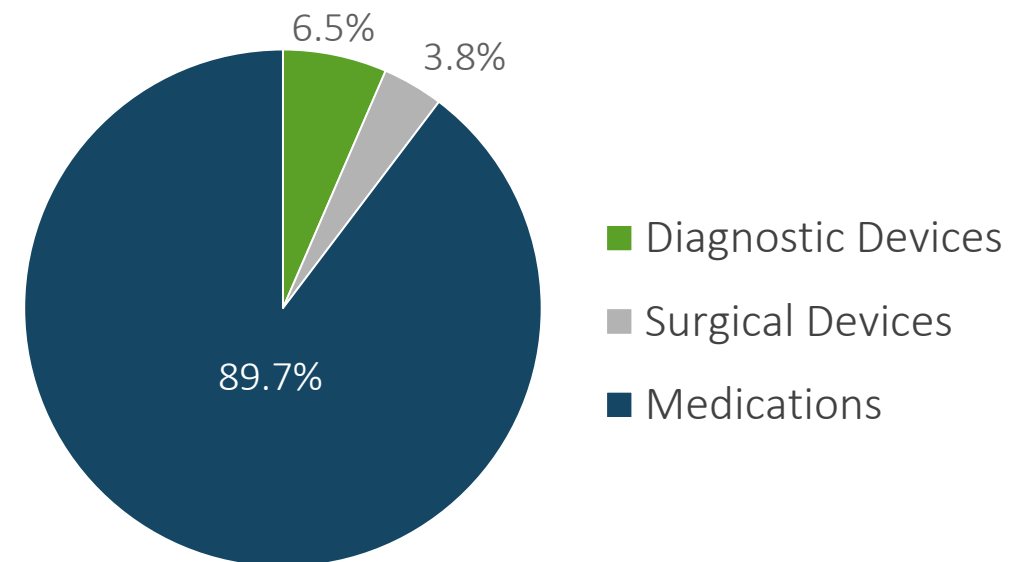


1 in **5** visits to
the eye doctor^{2,3}

High eye pressure leads to **nerve damage** and **blindness**



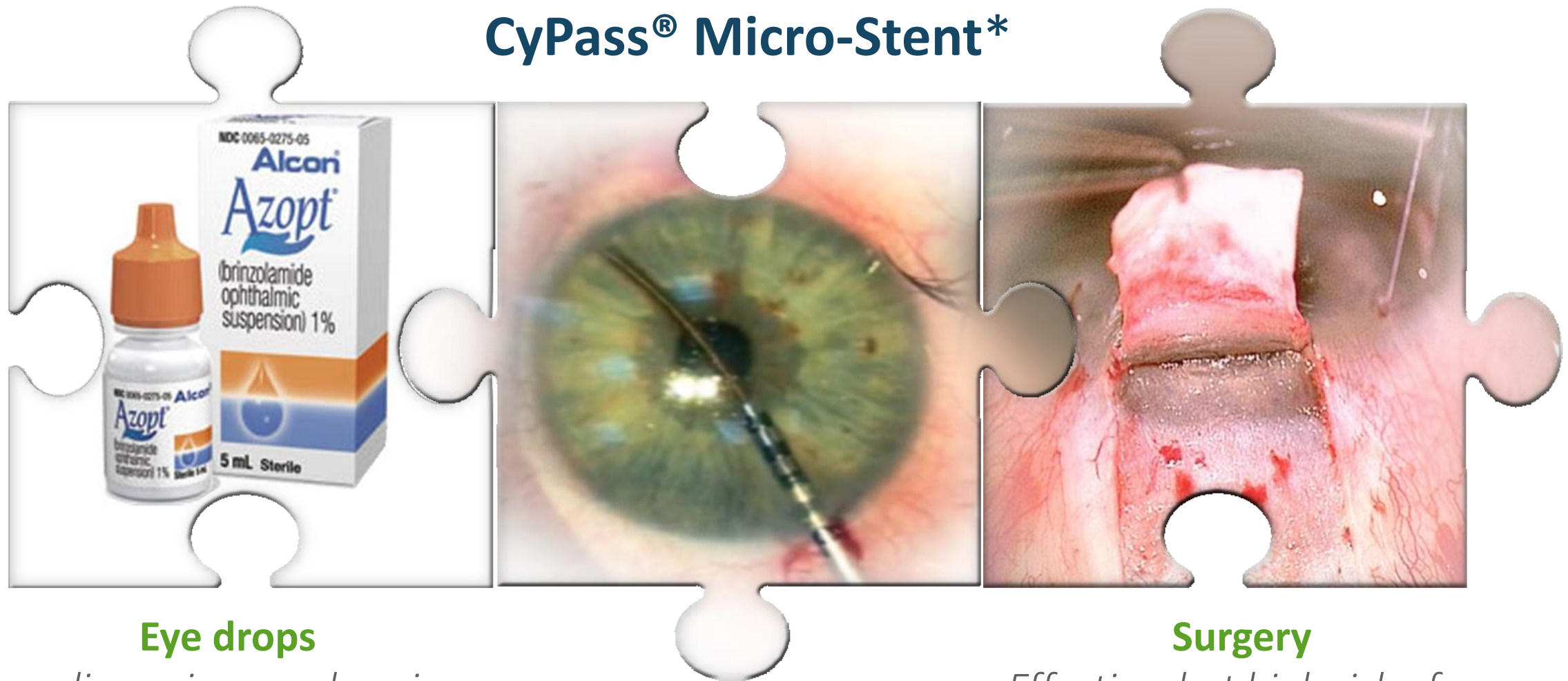
Mature therapeutics space: **\$6 billion** spent on glaucoma treatment each year⁴



1. Quigley and Broman "Number of people with glaucoma worldwide in 2010 and 2020", 2006; 2. Center for Disease Control and Prevention/National Center for Health Statistics, 2010 & 1995; 3. Center for Disease Control and Prevention/National Ambulatory Medical Care Survey Factsheet, 2010; 4. Market Scope 2012

What Could *Bridge the Gap*?

CyPass[®] Micro-Stent*



Eye drops

Compliance issues, chronic use damaging to eye surface

Surgery

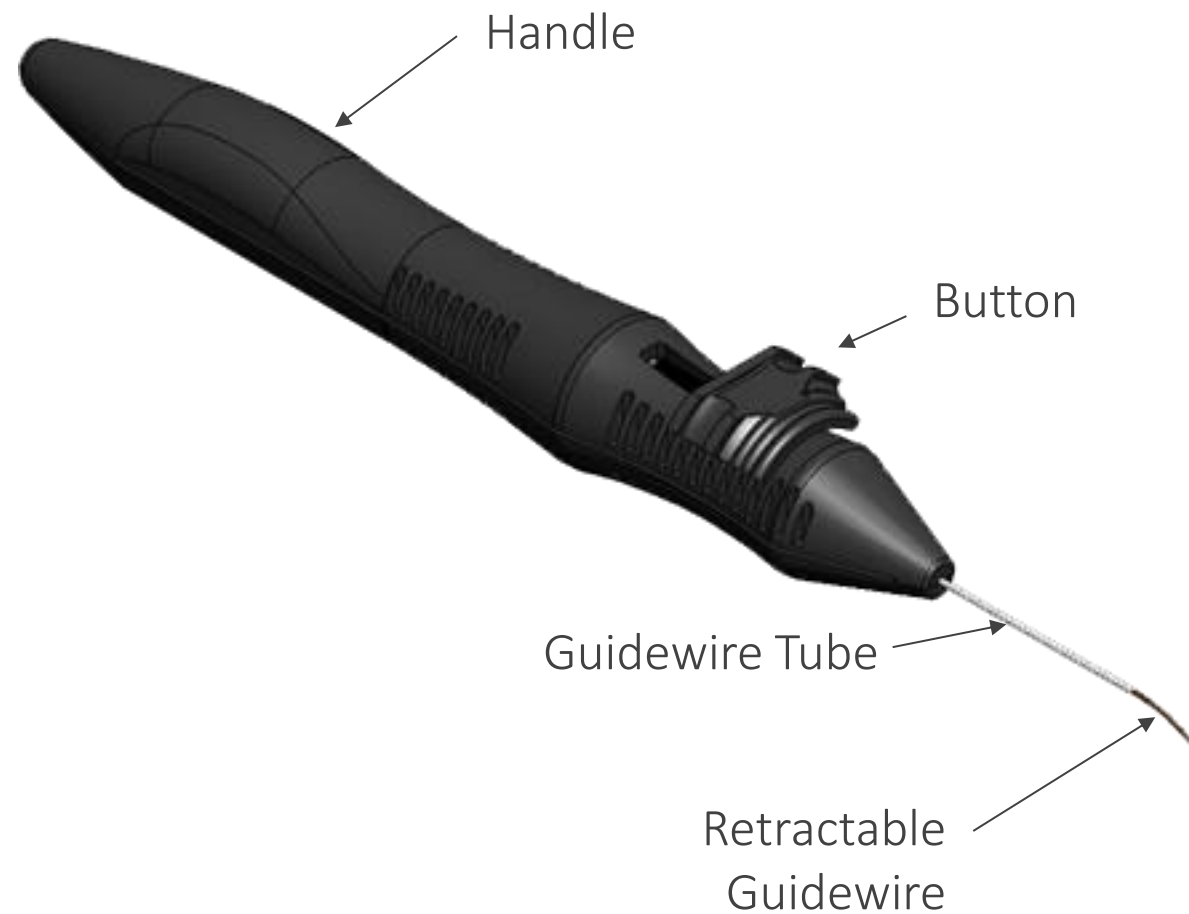
Effective, but high risk of complications

***Caution:** Investigational Device. Limited by Federal (USA) law to investigational use

CyPass System overview

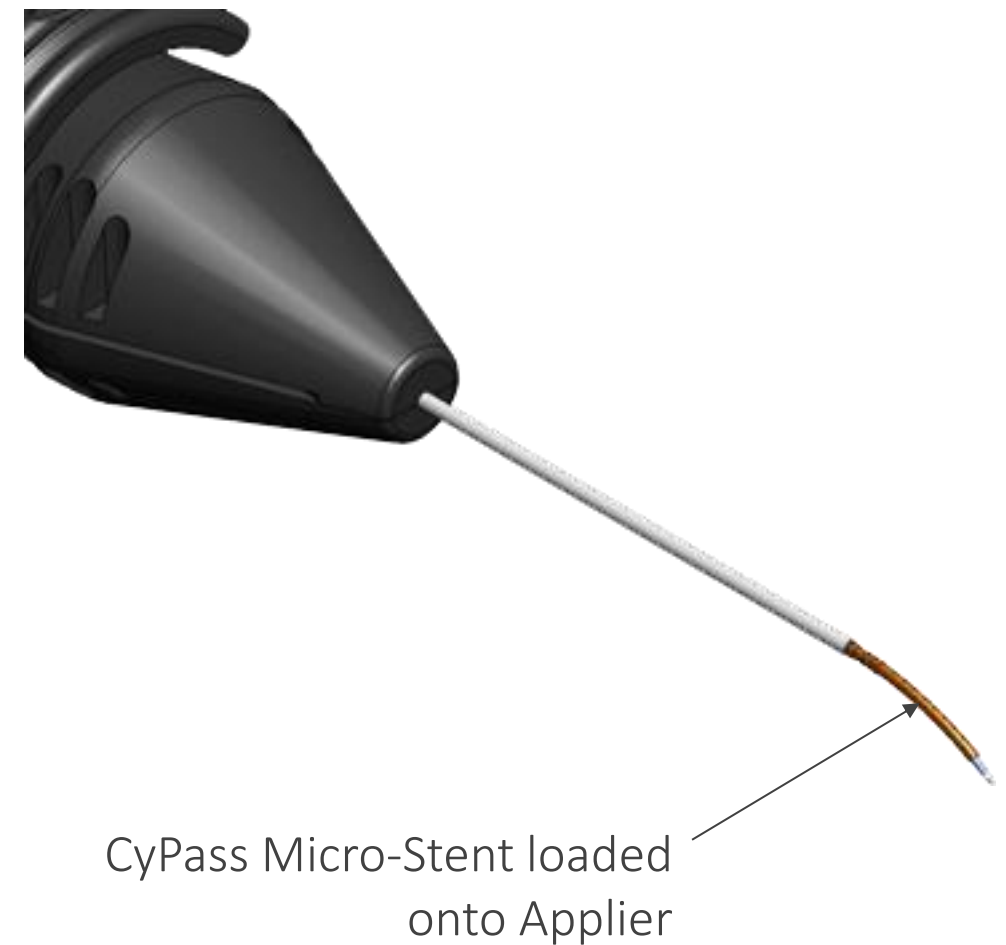
CyPass Applier

- Guidewire-driven
- Radius tip allows easy insertion

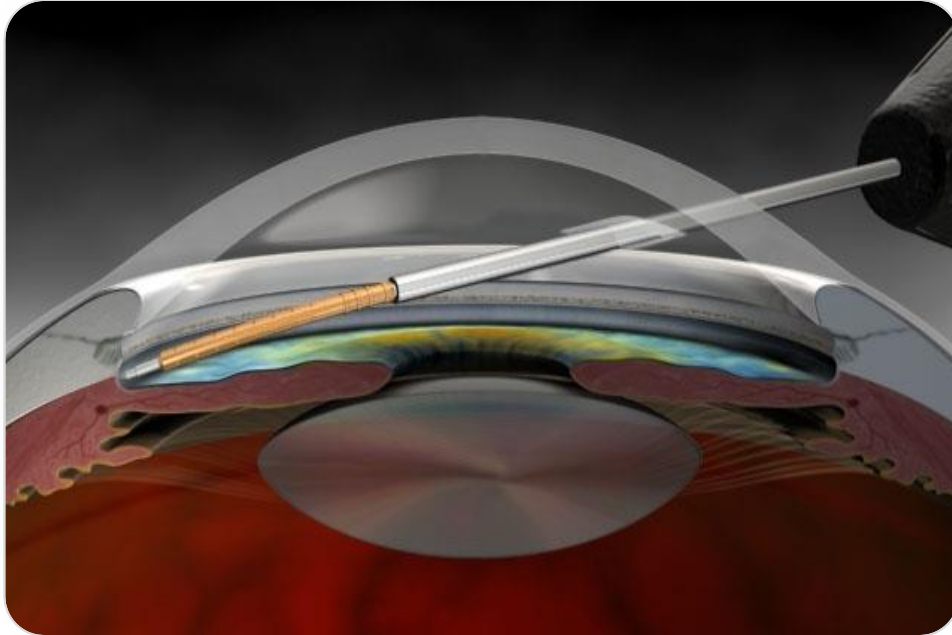


CyPass Micro-Stent

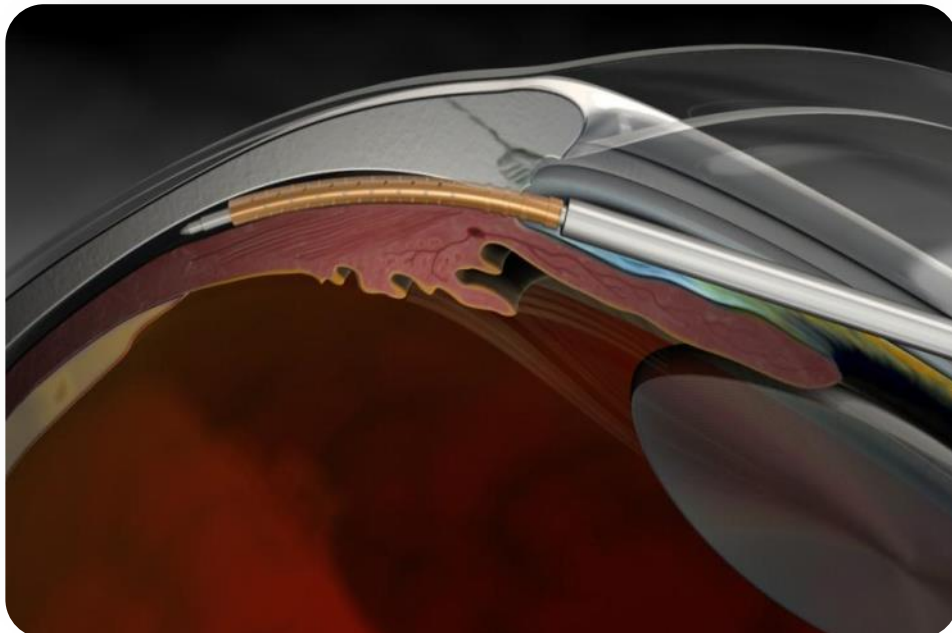
- Polyimide tube
- Retention features



CyPass Micro-Stent delivery

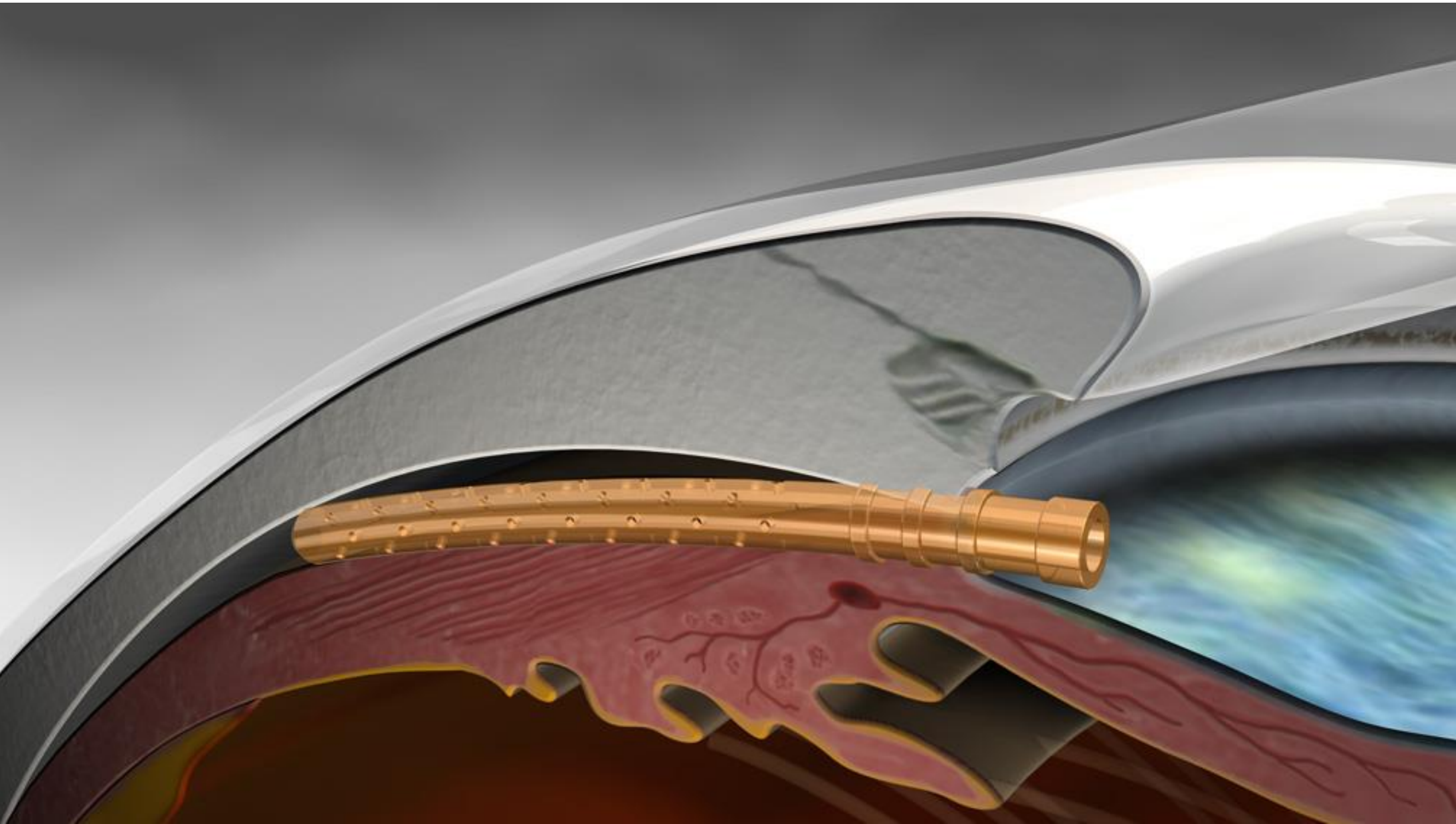


- Micro-invasive, ab interno approach
- 1.5 mm clear corneal incision or phaco incision



- Conjunctiva- and sclera-sparing
- Preserves trabecular meshwork

Diagram of the CyPass Micro-Stent in situ



CyPass Micro-Stent Research Program

>1000 cases to date across all studies

Pilot studies	Combination-Cataract and POAG	N=100	BJO ¹
CyCLE	EU Post-Market Combination-Cataract and POAG	n=565	JCRS ² , J Glaucoma ³ , Ophthalmologe ⁴ , Klin Monbl Augenheilkd ⁵
DUETTE	EU Post-Market POAG in Pre-Trab Patients	n=65	AJO (in press) ⁶
COMPASS	US-IDE Randomized Controlled Trial Combination-Cataract vs Cataract Alone	n=505	sub-analyses in JAMA Ophthalmol ^{7,8}
VISCOPASS	Randomized Controlled Trial CyPass + Viscoelastic	Phase I n= 63 Phase II n=90	Next-generation technology

8 peer-reviewed manuscripts published or in press

1. Saheb H. Br J Ophthalmol. 2014 Jan;98(1):19-23

2. Hoeh H. J Cataract Refract Surg. 2013 Mar;39(3):431-7.

3. Hoeh H. J Glaucoma. 2014 Oct 9.

4. Grisanti S. Ophthalmologe. 2014 Jun;111(6):548-52.

5. Höh H. Klin Monbl Augenheilkd. 2014 Apr;231(4):377-81.

6. Garcia-Feijoo. AJO. In Press.

7. Zhang ML. JAMA Ophthalmol. 2014 Aug;132(8):956-62.

8. Jampel HD. JAMA Ophthalmol. 2014 Apr 1;132(4):390-5

US-IDE study: COMPASS trial

1. Randomized, Controlled Study for FDA approved indication in POAG
2. Largest micro-invasive glaucoma surgery (MIGS) trial to complete by 2015 (505 subjects)
3. Key Trial Differentiators/Strengths:
 - Terminal wash out at 12 and 24 months to control medication bias
 - Strict criteria for re-introduction of medications
 - Strong primary endpoint outcome: 2-year diurnal unmedicated IOP change from baseline

		D0/Sx	D1	W1	M1	M3	M6	M12	M18	M24
Phaco (control)	133	✓	✓	✓	✓	✓	✓	✓	✓	✓
Phaco + CyPass	372	✓	✓	✓	✓	✓	✓	✓	✓	✓

Wash out B/L IOP

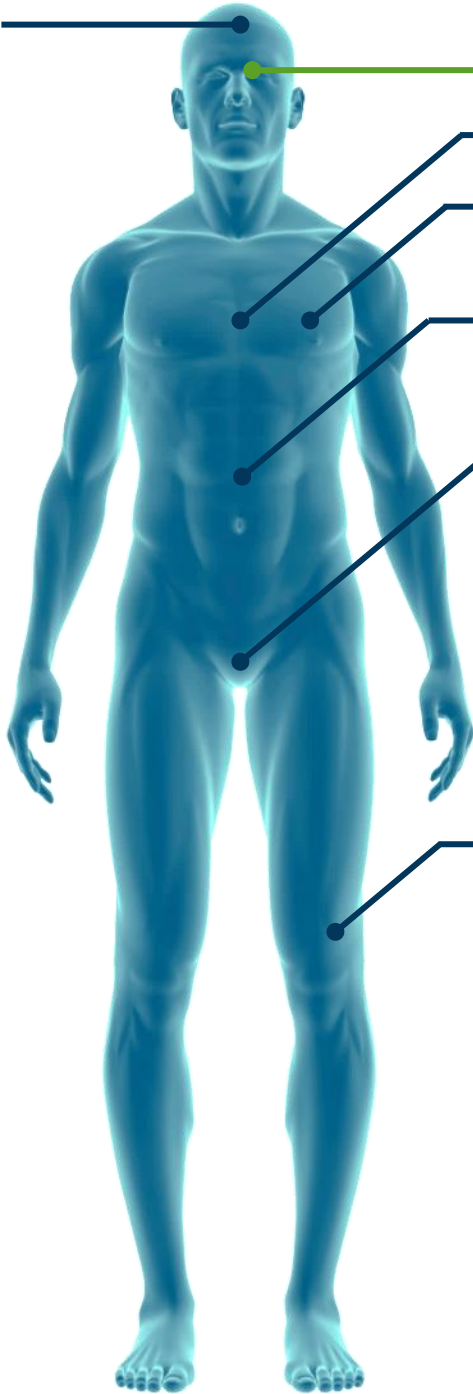
Primary Endpoint
 • Med Wash out
 • Diurnal IOP

Primary Endpoint
 • Med Wash out
 • Diurnal IOP

Stent Technology in Ophthalmology

The Next Frontier

Neurovascular



Cardiovascular

Pulmonary

Gastrointestinal

Urological/
Gynecological

Peripheral

Ophthalmology **MIGS**

