iStent infinite®

The Beginning of the
Interventional Glaucoma Revolution

infinite possibilities

iStent infinite® is designed to provide foundational, 24/7 therapy that gives you the power to deliver **optimized treatment for patients** with primary open angle glaucoma including those who have failed prior medical and surgical intervention, while minimizing the unwanted side effects of more invasive treatment options.[1]

The iStent infinite® pivotal trial

In the prospective, multicenter, 12-month pivotal trial, patients with open-angle glaucoma **who had failed prior surgical intervention** underwent standalone iStent infinite® implantation.[1]

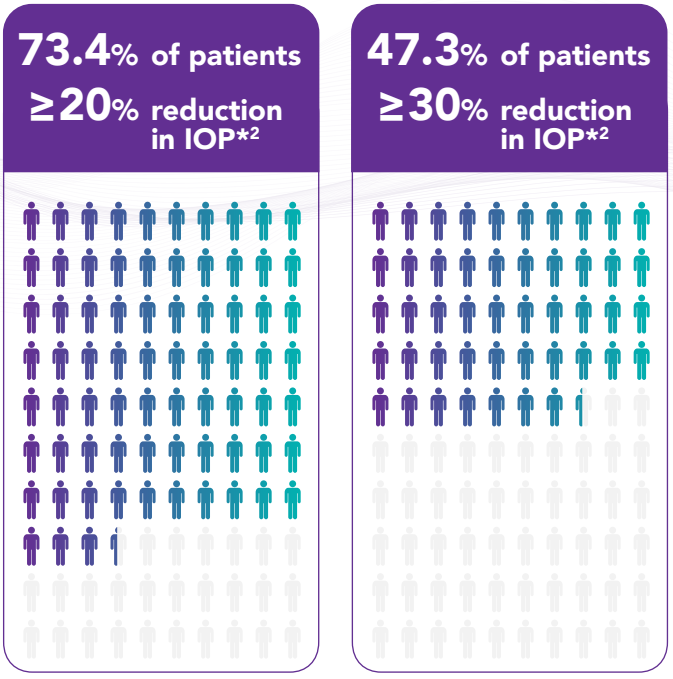
Average patient characteristics[1]:

- 2+ failed prior surgeries **(including trabeculectomy)**
- 3.0 mean medication burden
- 23.5 mmHg mean baseline IOP

91.7% **of subjects in the failed prior surgery group reduced or maintained medication burden at 12 months.[1]**

16.9 mmHg **mean diurnal IOP in patients who did not have an IOP-related SSI (n=57), corresponding to a mean reduction of 6.5 mmHg (27.7%).[2]**

Exceptional results in tough-to-treat patients at 12 months



Safety without compromise[1,2]

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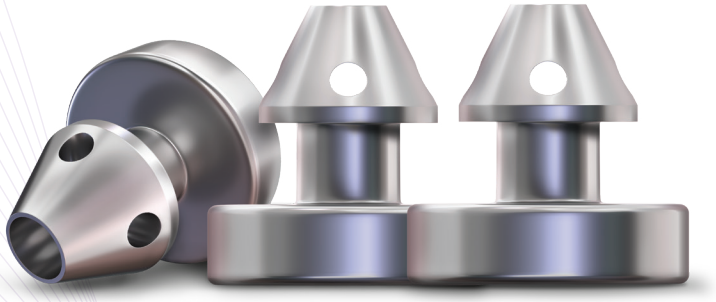
- HYPOTONY
- EXPLANTS
- CYCLODIALYSIS CLEFTS CREATED
- DEVICE-RELATED INTERVENTIONS

Only 4.9% of eyes (n=3) required secondary surgical intervention following iStent infinite® implantations through 12 months, despite multiple failed prior surgical interventions.[2]

*Reduction from baseline at 12 months on the same or fewer medications.

iStent infinite®

THE POWER OF 3



PARADIGM-CHANGING TECHNOLOGY

With 3 anatomically-designed stents preloaded into an elegant injector system, iStent infinite® is designed to:

- Provide powerful technology to deliver foundational, 24/7, long-term IOP control in patients with primary open angle glaucoma, pseudo-exfoliative glaucoma or pigmentary glaucoma[1]
- Safely offer interventional glaucoma, a truly micro-invasive alternative to medications and more invasive procedures, helping **address rampant rates of patient non-compliance** and disease progression
- Restore physiologic outflow by creating arcs of flow spanning **up to 8 clock hours (240°)** while minimizing tissue disruption—broad coverage vs other MIGS procedures[1]
- Provide you the **versatility to treat a variety of patients**

Experience the power to do more for your patients with iStent infinite®

Ordering Information:

Order #: iS3
1-844-GLAUKOS (452-8567)
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iSTENT TECHNOLOGIES
MORE THAN
ONE MILLION
iSTENT DEVICES
IMPLANTED WORLDWIDE

iStent infinite® Important Safety Information (ISI)

INDICATION FOR USE. The iStent infinite® is intended to reduce intraocular pressure safely and effectively in adult patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma or pigmentary glaucoma. The device is safe and effective when implanted in combination with or without cataract surgery in those subjects who require intraocular pressure reduction and/or would benefit from glaucoma medication reduction. The device may also be implanted in patients who continue to have elevated intraocular pressure despite prior treatment with glaucoma medications and/or conventional glaucoma surgery. **CONTRAINDICATIONS.** The iStent infinite® is contraindicated in eyes with angle-closure glaucoma where the angle has not been surgically opened, acute traumatic, malignant, active uveitic, or active neovascular glaucoma, discernible congenital anomalies of the anterior chamber (AC) angle, retrobulbar tumor, thyroid eye disease, or Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure. **WARNINGS.** Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, PAS, rubeosis, or conditions that would prohibit adequate visualization that could lead to improper placement of the stent and pose a hazard. **MRI INFORMATION.** The iStent infinite® is MR-Conditional, i.e., the device is safe for use in a specified MR environment under specified conditions; please see Directions for Use (DFU) label for details. **PRECAUTIONS.** The surgeon should monitor the patient postoperatively for proper maintenance of IOP. Three out of 61 participants (4.9%) in the pivotal clinical trial were phakic. Therefore, there is insufficient evidence to determine whether the clinical performance of the device may be different in those who are phakic versus in those who are pseudophakic. **ADVERSE EVENTS.** The most common postoperative adverse events reported in the iStent infinite® pivotal trial included IOP increase ≥ 10 mmHg vs. baseline IOP (8.2%), loss of BSCVA ≥ 2 lines (11.5%), ocular surface disease (11.5%), perioperative inflammation (6.6%) and visual field loss ≥ 2.5 dB (6.6%). **CAUTION.** Federal law restricts this device to sale by, or on the order of, a physician. Please see DFU for a complete list of contraindications, warnings, precautions, and adverse events.

REFERENCES

1. Glaukos Data on File. **2.** iStent infinite. Instructions for use. Glaukos Corporation; 2022.

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