HYDRUS®
MICROSTENT
Delivering A New Confidence

DO YOU HAVE GLAUCOMA AND NEED CATARACT SURGERY?

THE CONFIRM STUDY MAY BE RIGHT FOR YOU

HYDRUS®
MICROSTENT

Before asking about the CONFIRM Study, here are 3 things to know:

1. The Hydrus Microstent is for adult patients **45 years or older** undergoing cataract surgery who have mild to moderate primary open-angle glaucoma, a common type of glaucoma.

2. The Hydrus Microstent is a minimally invasive device that is placed during cataract surgery to help manage your glaucoma.

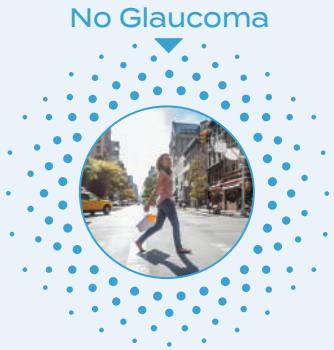
3. Hydrus Microstent may lower your IOP. In the weeks following your procedure, the study doctor will test your pressure to make this determination.

UNDERSTANDING GLAUCOMA

Glaucoma is a common eye disease that occurs due to increased pressure in the eye caused by a buildup of excess fluid. Treatment is aimed at lowering pressure to prevent further loss of vision.

Healthy Eye

In a healthy eye, a fluid called *aqueous humor* flows freely throughout the eye and travels through an internal drainage system.



Glaucoma

If the drainage system is blocked or partially obstructed, the natural pressure in your eye may increase.

TALK TO YOUR DOCTOR TO SEE IF THE CONFIRM STUDY IS RIGHT FOR YOU.

TREATING GLAUCOMA IN A UNIQUE WAY

Hydrus Microstent

Roughly the size of an eyelash, the highly flexible Hydrus Microstent is placed by a surgeon during cataract surgery using microscopic incisions and advanced equipment. The device opens a bypass through the trabecular meshwork, a common site of aqueous blockage in the eye. The device spans approximately 90 degrees within the canal. This coverage is designed to ensure that fluid reaches the eye's drainage system, which carries fluid from Schlemm's canal into the body's circulatory system and allows pressure to be lowered.

*Actual size is much, much smaller.

If you answer "yes" to each of these questions, you may be eligible to participate in the CONFIRM Study.

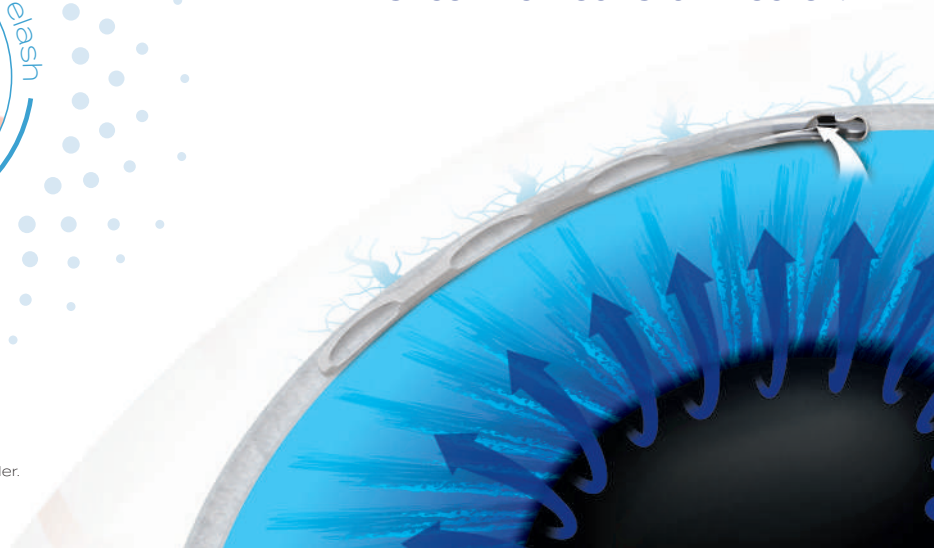
1. ARE YOU AT LEAST 45 YEARS OF AGE?
2. DO YOU REQUIRE CATARACT SURGERY?
3. ARE YOU CURRENTLY TAKING EYE DROPS FOR GLAUCOMA?

The Hydrus Microstent was approved by the FDA in 2018 for commercial use.

Those who qualify may receive:

- Follow-up care for two years.
- Compensation for costs related to time and travel.

FOR MORE INFORMATION, PLEASE CONTACT YOUR STUDY DOCTOR.



CAUTION: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE: The Hydrus Microstent is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild to moderate primary open-angle glaucoma (POAG).

CONTRAINDICATIONS: The Hydrus Microstent is contraindicated under the following circumstances or conditions: (1) In eyes with angle closure glaucoma; and (2) In eyes with traumatic, malignant, uveitic, or neovascular glaucoma or discernible congenital anomalies of the anterior chamber (AC) angle.

WARNINGS: Clear media for adequate visualization is required. Conditions such as corneal haze, corneal opacity or other conditions may inhibit gonioscopic view of the intended implant location. Gonioscopy should be performed prior to surgery to exclude congenital anomalies of the angle, peripheral anterior synechiae (PAS), angle closure, rubeosis and any other angle abnormalities that could lead to improper placement of the stent and pose a hazard.

PRECAUTIONS: The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. If the intraocular pressure is not controlled, the surgeon may recommend appropriate medication or other treatment. The safety and effectiveness of use of more than a single Hydrus Microstent has not been established. The Hydrus Microstent has not been established as an alternative to the primary treatment of glaucoma with medications.

ADVERSE EVENTS: Common post-operative adverse events reported in the randomized pivotal trial included partial or complete device obstruction (7.3%); worsening in visual field MD by > 2.5 dB compared with preoperative (4.3% vs 5.3% for cataract surgery alone); device malposition (1.4%); and BCVA loss of ≥ 2 ETDRS lines ≥ 3 months (1.4% vs 1.6% for cataract surgery alone). For additional adverse event information, please refer to the Instructions for Use.

MRI INFORMATION: The Hydrus Microstent is MR-Conditional meaning that the device is safe for use in a specified MR environment under specified conditions.

Ask your doctor for complete product information.

CP 18-001
ID-0097 Rev A
20190829

IVANTIS®
ivantisinc.com