



IMPORTANT PRODUCT INFORMATION

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. The surgeon should monitor the patient postoperatively for proper maintenance of intraocular pressure. The surgeon should periodically monitor the status of the microstent with gonioscopy to assess for the development of PAS, obstruction of the inlet, migration, or device-iris or device-cornea touch. The Hydrus Microstent is intended for implantation in conjunction with cataract surgery, which may impact corneal health. Therefore, caution is indicated in eyes with evidence of corneal compromise or with risk factors for corneal compromise following cataract surgery. Prior to implantation, patients with history of allergic reactions to nitinol, nickel or titanium should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials. **PRECAUTIONS:** If excessive resistance is encountered during the insertion of the microstent at any time during the procedure, discontinue use of the device. The safety and effectiveness of use of more than a single Hydrus Microstent has not been established. The safety and effectiveness of the Hydrus Microstent has not been established as an alternative to the primary treatment of glaucoma with medications, in patients 21 years or younger, eyes with significant prior trauma, eyes with abnormal anterior segment, eyes with chronic inflammation, eyes with glaucoma associated with vascular disorders, eyes with preexisting pseudophakia, eyes with pseudoexfoliative or pigmentary glaucoma, and when implantation is without concomitant cataract surgery with IOL implantation. Please see a complete list of Precautions in the Instructions for use. **ADVERSE EVENTS:** The most frequently reported finding in the randomized pivotal trial was peripheral anterior synechiae (PAS), with the cumulative rate at 5 years (14.6% vs 3.7% for cataract surgery alone). Other Hydrus postoperative adverse events reported at 5 years included partial or complete device obstruction (8.4%) and device malposition (1.4%). Additionally, there were no new reports of persistent anterior uveitis (2/369, 0.5% at 2 years) from 2 to 5 years postoperative. There were no reports of explanted Hydrus implants over the 5-year follow-up. 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. **Please see the Instructions for Use for complete product information.**

References: 1. Ahmed I, et al; HORIZON Investigators. Long-term Outcomes from the HORIZON Randomized Trial for a Schlemm's Canal Microstent in Combination Cataract and Glaucoma Surgery. [https://www.aaojournal.org/article/S0161-6420\(22\)00160-9/fulltext](https://www.aaojournal.org/article/S0161-6420(22)00160-9/fulltext)
2. Hydrus Microstent Instructions for Use

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Letters

Thoughts on Parental Leave

I would like to thank Ruth D. Williams, MD, for her editorial “Why Parental Leave Is Good Medicine” (Opinion, March).

I completely agree with her comments that paid time off for parental leave is very important. I would posit that it is important not only for those of us who are working in health care but also for those in other fields. Many highly profitable publicly traded companies offer very generous benefits far exceeding six weeks of paid time off—not only for parental leave but also for personal or family mental or physical health reasons.

Most for-profit companies can—to some degree—pass the costs of paid leave off to the consumer. But private medical practices typically do not have the market opportunity to charge their patients (customers) more as the benefits and compensation of employees improve. In other words, the work continues regardless of whether the doctor or employee is on leave. Do we then temporarily assign more work to the remaining group of providers when one or more providers go on leave? After all, the funding to support paid time off must come from work completed.

Furthermore, it is interesting that the for-profit Medicaid managed companies—such as Molina, Centene, Elevance, UnitedHealth Group, and CVS—all provide very generous employee benefits while providing Medicaid payments to medical practices for services at rates that are far below actual overhead costs. This is an unfair and unsustainable financial model.

Every family should be supported with policies that result in better outcomes, such as paid parental leave. If we, as a society, recognize and promote such priorities, then the funding should follow, no matter the size and location of the practice. This starts with policies that include funding and don't favor large, for-profit health insurance companies.

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One perspective that is missing from the discussion in “Why Parental Leave Is Good Medicine” (Opinion, March) is how to provide this benefit for those who practice in underserved areas, often in solo practice. The staff still needs to be paid, and patients still need timely care. Fewer ophthalmologists choose to work in rural, poor communities, leading to most practices closing without a successor, thus accelerating the decline in access.

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