



Is the Pressure of Glaucoma Getting to You?

Try a different approach with the
EX-PRESS® Glaucoma Filtration Device

Potential benefits with the EX-PRESS® Glaucoma Filtration Device.

- Maintained ocular pressure¹
- Effective IOP lowering¹
- Less glaucoma medication in the long term⁴
- Lower rates of post operative complications such as hypotony (*overly low pressure in the eye*) and chordial effusion (*vascular swelling in the back of the eye*)¹
- Faster visual recovery post-operation³
- Minimal tissue trauma^{2*}
- Reduced inflammation^{2*}

Am I a candidate?

The EX-PRESS® Glaucoma Filtration Device is indicated for patients who have not had success using medication alone and have had an unsuccessful prior conventional surgery such as laser surgery (ALT or SLT).

If you have further questions or would like more information on the benefits and risks of the EX-PRESS® Glaucoma Filtration Device, please talk to your doctor. He or she can also tell you how best to prepare before the surgery and what you should do afterward to make sure you have the best outcome possible.



What causes glaucoma?

Glaucoma is a common condition, affecting more than 60 million people around the world. It occurs when an excess amount of eye fluid, also called aqueous, is formed because regular drainage in the eye is damaged. This causes the aqueous to accumulate and build up pressure. The pressure can damage the optic nerve, resulting in a decrease in vision.

Some facts you should know:

- Glaucoma is the second leading cause of blindness worldwide.
- Open-angle glaucoma accounts for 90% of cases.
- It is generally painless and occurs slowly over time.

Help me learn more.

If your doctor has diagnosed you with glaucoma, you may have tried different treatments in the past, like eye drops and surgery. If these haven't helped, there are other options.

One alternative treatment to help control the symptoms of glaucoma is the EX-PRESS® Glaucoma Filtration Device, which has been implanted in 125,000 patients. It has been specifically designed to help relieve the increased pressure within the eye.



The EX-PRESS® Glaucoma Filtration Device is intended to reduce intraocular pressure in glaucoma patients where medical and conventional surgical treatments have failed.

Caution: Federal (USA) law restricts this device to sale by, or on order of, a physician.

Introducing the EX-PRESS® Glaucoma Filtration Device.

The EX-PRESS® Glaucoma Filtration Device is a tiny implant that is about the size of a grain of rice. It is placed between the inner region of the eye and the outer region.



The EX-PRESS® Glaucoma Filtration Device.
So small, you won't even know it's there.

This device bypasses the normal drainage system that has been damaged and provides an alternative route for the built-up aqueous to successfully drain out of the eye. The result is precise control of fluid to keep pressure in the eye at a healthy level.

After the EX-PRESS® Glaucoma Filtration Device surgery, typically patients experience:

- Lower pressure in the eye⁴
- Less glaucoma medication in the long term⁴
- Lower rates of post operative complications such as hypotony and chordial effusion¹
- A faster visual recovery³

This procedure can also be performed together with cataract surgery.⁵

What can I expect before and after surgery?

Before

- Eye drops will be given to numb your eye in the operating room.
- Your eye will be cleaned and a sterile drape placed over your face and body with one eye left uncovered, which is held open to prevent blinking.
- Sedating medication can also be given to you through an IV for comfort.

After

- A patch is placed over your eye, which will be removed at the first post-operative doctor's visit.
- Normal activities should be limited for a few weeks post-surgery, and you should avoid strenuous activity like heavy lifting.
- Sutures are normally removed in 3 weeks.
- You will have checkups fairly often during the first 8 weeks.
- Multiple eye drops will be needed during the first 6-8 weeks, but many patients can stop using them after the healing period is over and your doctor advises to do so.



Unlike trabeculectomy that usually requires a small part of the iris to be removed, the EX-PRESS® Glaucoma Filtration Device can generally not be seen in the eye after implantation. With the EX-PRESS® Glaucoma Filtration Device patients have an IOP lowering option without unsightly cosmetic impacts.

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INDICATION: The EX-PRESS® Glaucoma Filtration Device is intended to reduce intraocular pressure in glaucoma patients where medical and conventional surgical treatments have failed.

CLINICAL STUDY INFORMATION: A clinical study was performed with the EX-PRESS® Glaucoma Filtration Device versions R-30 and R-50. The study was a prospective, open-label multi-center study of 113 open angle glaucoma patients with a follow-up period of one year. Results indicated an 80.4% overall success for the per-protocol cohort (R-30 and R-50, n=58) at one year, where overall success was defined as an IOP reduction greater than 20% from baseline with or without medications. Results indicated a 75.9% overall success for the per-protocol cohort (R-30 and R-50, n=58) at one year, where overall success was defined as an IOP of less than 21 mmHg with or without medications. The mean IOP reduction at one year was 33.8%. The percentage reduction from baseline was greater than 28% for the R-30 version and greater than 40% for the R-50 version.

The overall average number of glaucoma medications dropped significantly from 1.55 pre-operative to 0.52 medications at one-year postoperative.

The clinical study was not designed to compare between the various versions of the EX-PRESS® Glaucoma Filtration Device. The selection of the appropriate version is according to the doctor's discretion.

The most commonly reported adverse events included the need for further filtering surgery, device explantation, bleb revision and iris touch. Reasons for device explantation included flat anterior chamber with hypotony, device exposure from erosion, and poor efficacy. Other adverse events such as, but not limited to, corneal and retinal complications, uveitis, and significant reduction in visual acuity, may occur as well.

CONTRAINDICATIONS: The use of this device is contraindicated if one or more of the following conditions exist: Presence of ocular disease such as uveitis, ocular infection, severe dry eye, severe blepharitis; pre-existing ocular or systemic pathology that, in the opinion of the surgeon, is likely to cause postoperative complications following implantation of the device or patients diagnosed with angle closure glaucoma.

WARNINGS/PRECAUTIONS: The surgeon should be familiar with the instructions for use. The integrity of the package should be examined prior to use and the device should not be used if the package is damaged and sterility is compromised. This device is for single use only. MRI of the head is permitted, however not recommended, in the first two weeks post implantation.

ATTENTION: Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

* Compared to trabeculectomy.

¹ Maris JG Jr, Ishida K, Netland PA. Comparison of trabeculectomy with Ex-PRESS miniature glaucoma device implanted under scleral flap. *J Glaucoma*. 2007;16(1):14-19.

² Sampson EM, Esson DW, Schultz GS, Sherwood MB. Expression of transforming growth factor-b2 following sclerostomy and ExPRESS R glaucoma drainage implant beneath a scleral flap in a rabbit model. *Invest Ophthalmol Vis Sci*. 2005;46:E-Abstract 52.

³ Good, T.J., Kahook, M.Y.. Assessment of Bleb Morphologic Features and Postoperative Outcomes after Ex-Press Drainage Device Implantation versus Trabeculectomy. *American Journal of Ophthalmology*. 2011. 151:507-514.

⁴ De Jong L, Lafuma A, Aguadé AS, Berdeaux G, Five-year extension of a clinical trial comparing the EX-PRESS® glaucoma filtration device and trabeculectomy in primary open-angle glaucoma. *Clinical Ophthalmology* 2011;5 527-533

⁵ Kanner EM, Netland PA, Sarkisian SR Jr, Du H. EX-PRESS® miniature glaucoma device implanted under a scleral flap alone or combined with phacoemulsification cataract surgery *J Glaucoma* 2009 Aug;18(6):488-91.

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