EX-PRESS® Glaucoma Filtration Device
Surgical Procedure
Surgical Recommendations

- EX-PRESS® Glaucoma Filtration Device preloaded device (plus 1 back-up)
- Sterile caliper
- Lid speculum
- Corneal forceps
- 0.12 forceps
- Tying forceps, small and large
- Microspone™ surgical sponge with OCUCEL® corneal shield
- 15ml sterile irrigating solution
- ALCON® A-OK® 15 degree Standard Angle Knife (8065921501)
- ALCON® ClearCut™ HP Crescent Knife or ClearCut™ Dual Bevel Crescent Knife
- Mosquito forceps, small
- 4 x 4 gauze pads
- Vannas scissors
- Westcott scissors
- Bi-polar diathermy pencil (recommend pointed)
- Wound treating agent determined by physician
- Pierse fixation forceps
- 25G EDGEPLUS® Trocar Blade or 26G needle
- 6-0 Silk suture (as Bridal suture)
- 10-0 Nylon and 8-0 Vicryl suture
- Fluorescein strips
1. Create peritomy.

2. Create 33-50% depth scleral flap.

3. Apply appropriate wound treating agent at surgeon's discretion.

4. Copiously rinse with sterile irrigating solution, then create paracentesis.
Release 6-0 Silk (as a Bridle suture). Create pre-incision (25G-26G needle). Insertion point at lower end of the blue-grey zone. Always enter parallel to iris!

Insert device through pre-incision site with tip pointed slightly downward. Grasp sclera for good counter-traction with 0.12 forceps in off-hand.

After device has locked in, slide finger back on injector to feel trigger button. Push directly downward for a soft release.

Verify device position and aqueous outflow.
Suture scleral flap into position and recheck outflow (titrate suture tension as necessary).

Suture conjunctiva closed - check for water tight with fluorescein strip.

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.

See back cover for important safety information.
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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 iridectomy. 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.

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