

# EX-PRESS® Glaucoma Filtration Device

**EXPRESS**  
Glaucoma Filtration Device

The EX-PRESS® Glaucoma Filtration Device Preloaded on EDS Versions R-50, P-50, and P-200

## INSTRUCTIONS FOR USE

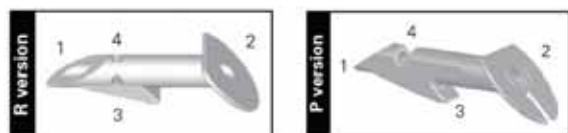


Figure 1: The EX-PRESS® Glaucoma Filtration Device Preloaded on EDS

## DESCRIPTION

The EX-PRESS® is a Glaucoma Filtration Device designed to regulate intraocular pressure in eyes suffering from glaucoma. The concept behind the EX-PRESS® Glaucoma Filtration Device is to divert aqueous humor through the implant from the anterior chamber to an intrascleral space - the bleb. The EX-PRESS® Glaucoma Filtration Device is manufactured from implantable stainless steel. It consists of a 2-3mm long and 0.4mm diameter tube, which connects the anterior chamber to the intrascleral space. Despite its miniature size, the EX-PRESS® Glaucoma Filtration Device features several major structural elements:

1. A cannula for draining aqueous humor from the anterior chamber to the intrascleral space.
2. A plate to prevent excessive penetration.
3. A spur to prevent extrusion of the EX-PRESS® Glaucoma Filtration Device from the eye.
4. Reserve orifices near the distal end, which constitute an alternative conduit for aqueous humor drainage in case of occlusion of the primary (axial) opening of the cannula by the iris.



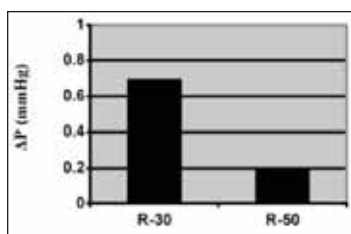
The EX-PRESS® Glaucoma Filtration Device is preloaded on a specially designed disposable introducer, the EX-PRESS® Delivery System (EDS). The EDS is an inserter designed to maintain the correct orientation of the EX-PRESS® Glaucoma Filtration Device throughout the implantation procedure. The EDS allows the surgeon better control of the device as it is released. The EDS enables easy insertion for either right or left handed physicians, using only one finger for simple, consistent device release. The EDS is intended for single use.

The following versions of the EX-PRESS® Glaucoma Filtration Device are commercially available: R-50, P-50 and P-200.

## INDICATIONS FOR USE

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 R-30 and R-50 versions. As these versions have similar performance to the P models, the results are relevant for these models as well. The study was a prospective, open-label multi-center study conducted at 14 international sites in 8 countries.

There were 113 open angle glaucoma patients enrolled into 3 protocols.

The three protocols included the following:

- STS-97-01 (n=56) - failed medical therapy or laser trabeculoplasty patients
- STS-99-COM (n=36) - failed medical therapy or laser trabeculoplasty patients who underwent a combined procedure of EX-PRESS® Glaucoma Filtration Device implantation and cataract surgery
- STS-99-TRA (n=21) - failed filtering surgery (trabeculectomy) patients

The follow-up period was one year with intermediate scheduled examinations on the 1st and 7th postoperative days and on the 4th, 9th, 13th, 26th, and 39th weeks; the final visit was on the 52nd week. The examinations included tonometry, gonioscopy, and a slit-lamp examination. The clinical study was conducted in accordance with EN 540 Guidelines and the Declarations of Helsinki, and the local laws and regulations of the countries where the study was conducted.

The safety and effectiveness evaluation was done on a total of 113 patients implanted with the R-30 and R-50 versions; 58 consecutive patients completed a one-year follow-up (defined as Per Protocol cohort).

## COMPLICATIONS AND ADVERSE EVENTS

Incidence of related Adverse Events stratified by device version (Intent to Treat Cohort) follows:

| Related Adverse Events                   | Device |       |      |       |     |       |
|------------------------------------------|--------|-------|------|-------|-----|-------|
|                                          | R-30   |       | R-50 |       | All |       |
|                                          | N      | %     | N    | %     | N   | %     |
| Glaucoma filtering surgery               | 9      | 13.24 | 5    | 11.11 | 14  | 12.39 |
| Device removal                           | 10     | 14.71 | 4    | 8.89  | 14  | 12.39 |
| Revision of bleb without antimetabolites | 5      | 7.35  | 7    | 15.56 | 12  | 10.62 |
| Device-Iris touch                        | 9      | 13.24 | 2    | 4.44  | 11  | 9.73  |
| Hyphema < 2 mm                           | 5      | 7.35  | 5    | 11.11 | 10  | 8.85  |
| Shallow AC                               | 6      | 8.82  | 3    | 6.67  | 9   | 7.96  |
| Hypotony                                 | 2      | 2.94  | 6    | 13.33 | 8   | 7.08  |
| Revision of bleb with antimetabolites    | 2      | 2.94  | 6    | 13.33 | 8   | 7.08  |
| Tenon cyst                               | 3      | 4.41  | 4    | 8.89  | 7   | 6.19  |
| Corneal complication                     | 3      | 4.41  | 4    | 8.89  | 7   | 6.19  |
| AC reformation                           | 4      | 5.88  | 2    | 4.44  | 6   | 5.31  |
| Device exposure                          | 6      | 8.82  | 0    | 0     | 6   | 5.31  |
| Bleb leakage                             | 2      | 2.94  | 3    | 6.67  | 5   | 4.42  |
| Cataract                                 | 5      | 7.35  | 0    | 0     | 5   | 4.42  |
| Flat AC                                  | 2      | 2.94  | 3    | 6.67  | 5   | 4.42  |
| Device malfunction                       | 3      | 4.41  | 1    | 2.22  | 4   | 3.54  |
| Choroidal complication                   | 2      | 2.94  | 1    | 2.22  | 3   | 2.65  |
| Hyphema                                  | 1      | 1.47  | 2    | 4.44  | 3   | 2.65  |
| Choroidal hemorrhage or effusion         | 1      | 1.47  | 2    | 4.44  | 3   | 2.65  |
| Device reposition                        | 1      | 1.47  | 2    | 4.44  | 3   | 2.65  |
| Conjunctival complication                | 2      | 2.94  | 0    | 0     | 2   | 1.77  |
| Device-Cornea touch                      | 2      | 2.94  | 0    | 0     | 2   | 1.77  |
| Release of device-iris touch by laser    | 1      | 1.47  | 1    | 2.22  | 2   | 1.77  |
| Faulty introduction                      | 1      | 1.47  | 1    | 2.22  | 2   | 1.77  |
| Eye pain                                 | 2      | 2.94  | 0    | 0     | 2   | 1.77  |
| Device obstruction                       | 0      | 0     | 1    | 2.22  | 1   | 0.88  |
| GDD implant                              | 0      | 0     | 1    | 2.22  | 1   | 0.88  |
| Device partial exposure                  | 1      | 1.47  | 0    | 0     | 1   | 0.88  |
| Iris depigmentation under device         | 1      | 1.47  | 0    | 0     | 1   | 0.88  |
| Argon laser trabeculoplasty              | 1      | 1.47  | 0    | 0     | 1   | 0.88  |
| Headache                                 | 0      | 0     | 1    | 2.22  | 1   | 0.88  |
| All                                      | 92     |       | 67   |       | 159 |       |

Adverse events reported for other glaucoma penetrating surgical procedures, such as but not limited to, corneal and retinal complications, uveitis, and significant reduction in visual acuity, may occur as well. The safety profile was indistinguishable between the two versions. Reasons for device explantation included flat anterior chamber with hypotony, device exposure from erosion, and poor efficacy.

## EFFICACY

The cumulative probability of success for this cohort for versions R-30 and R-50 at one year was 75% and 79%, respectively.

| Criteria/Cohort Per | Protocol cohort |      |                     |
|---------------------|-----------------|------|---------------------|
| Version             | R-30            | R-50 | All (weighted mean) |
| Kaplan-Meier        | 75%             | 79%  | 77%                 |
| IOP reduction > 20% |                 |      |                     |
| Kaplan-Meier        | 78%             | 88%  | 83%                 |
| IOP < 21 mmHg       |                 |      |                     |

Note: Kaplan-Meier analysis evaluates time to failure.

Results from clinical studies indicated a 77% cumulative probability of success for the Per Protocol cohort (R-30 and R-50, n=58) at one year (Kaplan-Meier survival curve), where failure was defined as an IOP reduction less than 20% from baseline with or without medications (overall success).

Results from clinical studies indicated an 83% cumulative probability of success for the Per Protocol cohort (R-30 and R-50, n=58) at one year (Kaplan-Meier survival curve), where failure was defined as an IOP < 21 mmHg with or without medications (overall success).

The overall success for this cohort for versions R-30 and R-50 version at one year was:

| Criteria/Cohort Per | Protocol cohort |        |                     |
|---------------------|-----------------|--------|---------------------|
| Version             | R-30            | R-50   | All (weighted mean) |
| Kaplan-Meier        | 68.80%          | 95.80% | 80.40%              |
| IOP reduction > 20% |                 |        |                     |
| Kaplan-Meier        | 65.60%          | 88.50% | 75.90%              |
| IOP < 21 mmHg       |                 |        |                     |

Note: Overall success is defined as success with or without IOP lowering medications.

Results from clinical studies 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 from clinical studies 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 < 21 mmHg with or without medications.

The mean IOP reduction at one year for this cohort 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.

| % IOP reduction at 12 months |       |       |      |
|------------------------------|-------|-------|------|
| Per Protocol cohort          |       |       |      |
| Version                      | R-30  | R-50  | All  |
| Mean                         | 28.68 | 40.66 | 33.8 |
| N                            | 32    | 24    | 56   |

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

| Number of medications at one year (Mean) |      |      |      |
|------------------------------------------|------|------|------|
| Per Protocol cohort                      |      |      |      |
| Version                                  | R-30 | R-50 | All  |
| Baseline                                 | 1.47 | 1.65 | 1.55 |
| One year                                 | 0.63 | 0.38 | 0.52 |
| N                                        | 32   | 26   | 58   |

## GUIDANCE REGARDING THE SELECTION OF THE APPROPRIATE VERSION

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.

## CONTRAINDICATIONS

The implantation of the EX-PRESS® Glaucoma Filtration 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.
- Patient diagnosed with angle closure glaucoma.

## HOW SUPPLIED

The EX-PRESS® Glaucoma Filtration Device preloaded on the EDS is supplied sterile in a sealed pouch (Fig.1). The device and the EDS have been sterilized by gamma irradiation and are intended for single use only.

## WARNINGS, PRECAUTIONS

The implanting surgeon should be familiar with the instructions for use.

The integrity of the package, the EX-PRESS® Glaucoma Filtration Device and the EDS should be examined. If the package is opened but not used, the implant should be

returned to the manufacturer for exchange.

The EX-PRESS® Glaucoma Filtration Device and EDS should not be used if sterility or performance is compromised. The detent button of the EDS should not be pressed until implantation, since it is for single use only.

MRI of the head is permitted, however not recommended, in the first two weeks post implantation.

## EQUIPMENT REQUIRED

One device loaded on EDS, conventional ophthalmic microsurgical instruments and a surgical microscope. A 25-27G needle is required for performing a pre-incision for the EX-PRESS® Glaucoma Filtration Device.

## MODE OF ACTION

The EX-PRESS® Glaucoma Filtration Device is implanted at the limbus after insertion under scleral flap (see Figure 2).

Its distal tip penetrates into the anterior chamber, while its proximal end is located under the scleral flap. The EX-PRESS® Glaucoma Filtration Device controls intraocular pressure by allowing a limited outflow of aqueous humor into the intrascleral space. The extent of drainage, and thus the intraocular pressure, is controlled by the hydrodynamic structure of the device.



Figure 2: Implantation of the EX-PRESS® Glaucoma Filtration Device

## IMPLANTATION PROCEDURE

Local or topical anesthesia is administered and the eye is prepared and covered using conventional sterile procedures. Implantation is performed using a special introducer (EDS), conventional microsurgical instruments and a surgical microscope.

The operation can be performed with viscoelastic material alone or with the use of a mini A/C maintainer and viscoelastic. The EX-PRESS® Glaucoma Filtration Device, preloaded on the EDS, is inserted into the anterior chamber at the limbus through the sclera under the scleral flap.

The implantation procedure may be performed as follows:

## EX-PRESS® GLAUCOMA FILTRATION DEVICE IMPLANTATION USING THE EX-PRESS® DELIVERY SYSTEM (EDS)

1. Create a 6mm long fornix-based conjunctival flap in the upper quadrants.
2. Create a limbal-based square (5x5mm) or trapezoidal (5x5x2mm) scleral flap extending into clear cornea. The depth of the flap should be ± 50% of scleral thickness.
3. Application of appropriate wound treating agent onto the sclerectomy bed at the surgeon's discretion.
4. Penetrate into the anterior chamber, creating a track incision with a 25-27G needle in the grey zone parallel to the iris plane.
5. Loosen and lubricate the EX-PRESS® Glaucoma Filtration Device with BSS® Solution.
6. Implant the EX-PRESS® Glaucoma Filtration Device loaded on the EDS, through that pre-incision.
7. Apply full depression of the EDS detent button, allowing a smooth release of the EX-PRESS® Glaucoma Filtration Device.
8. Release the EDS detent button. The wire is permanently indented and fully retracted (single use only).
9. Withdraw the EDS.
10. Tuck the plate under the scleral flap, and verify its position.
11. Suture the scleral flap in at least 3 or 4 positions.
12. Reposition the conjunctiva with one or two sutures at the limbus.
13. Fill the anterior chamber with viscoelastic material.
14. Inject antibiotics and steroids subconjunctivally (optional).

After the implantation procedure, antibiotics are administered topically, the eye is covered with a pad and the patient is discharged.

Patients must be followed closely during the first year after implantation (at least 4 times), and at least once a year during the device's lifetime.



See instructions for use



Sterilized by Radiation



Do not Reuse



Federal (USA) law restricts this device for sale by or on the order of a physician

## Manufactured by:

Alcon Laboratories, Inc.  
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