DESCRIPTION
The EX-PRESS™ Glaucoma Filtration Device is 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 a subscleral space. The EX-PRESS™ Glaucoma Filtration Device is manufactured from implantable stainless steel. It consists of a 2-3 mm long and 0.4 mm diameter tube, which connects the anterior chamber to the subscleral space.

The EX-PRESS™ Glaucoma Filtration Device features several major structural elements (Figure 2):
1. A cannula for draining aqueous humor from the anterior chamber to the subscleral space.
2. A plate to prevent excessive penetration.
3. A spur to prevent extrusion of the implant from the eye.
4. Reserve orifices at 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. The EX-PRESS™ Delivery System is an inserter designed to maintain the correct orientation of the EX-PRESS™ Glaucoma Filtration Device throughout the implantation procedure. The EX-PRESS™ Delivery System allows the surgeon better control of the implant as it is released. The EX-PRESS™ Delivery System enables easy insertion for either right or left handed physicians, using only one finger for simple, consistent device release. The EX-PRESS™ Delivery System is intended for single use.

INDICATIONS FOR USE
The EX-PRESS™ Glaucoma Filtration Device is indicated as a treatment for patients suffering from glaucoma, and for whom there is an indication, according to the physician’s judgment, for filtering surgery.
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 EX-PRESS™ Delivery System (Figure. 1) is supplied sterile in a sealed package. The device and the EX-PRESS™ Delivery System 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 EX-PRESS™ Glaucoma Filtration Device should not be implanted in eyes with very thin conjunctiva because of a potential risk of conjunctival erosion. The integrity of the package of the EX-PRESS™ Glaucoma Filtration Device and the EX-PRESS™ Delivery System should be examined. If the package is opened but not used, the device should be returned to the manufacturer for exchange. The EX-PRESS™ Glaucoma Filtration Device and EX-PRESS™ Delivery System should not be used if sterility or performance is compromised. The detent button of the EX-PRESS™ Delivery System 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.

MR Conditional
Regarding the Magnetic Resonance (MR) status of the implant:
 a. The device is MR-Conditional according to the terminology specified in the American Society for Testing and Material (ASTM) International, Designation: F2503-05. MR-Conditional means that the device is safe for use in a specified MR environment under specified conditions (see below); however, it may not be safe to use in MR environments that do not match these specified conditions.
b. A patient with this device can be scanned safely immediately after placement under the following specified conditions:
   i. Static magnetic field: 3-Tesla or less
   ii. Maximum spatial magnetic field gradient: 720-Gauss/cm or less
   iii. Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/k for 15 minutes of scanning.

POTENTIAL COMPLICATIONS AND SIDE EFFECTS
The complications during or following the implantation may include:
• Flat or shallow anterior chamber
• Choroidal detachment of short or long duration
• Significant reduction in visual acuity
• Development of scarring tissue at surgical site
• Conjunctival erosion
• Hyphema < 2mm
EQUIPMENT REQUIRED
One device loaded on the EX-PRESS™ Delivery System, 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 the scleral flap (Figure 3). Its distal tip penetrates into the anterior chamber, while the 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.

IMPLANTATION PROCEDURE
Local or topical anesthesia is administered and the eye is prepared and covered using conventional sterile procedures. Implantation is performed using the EX-PRESS™ Delivery System, 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 EX-PRESS™ Delivery System is inserted into the anterior chamber at the limbus through the sclera under the scleral flap.

The implantation procedure may be performed as follows:
1. Create a 6mm long fornix-based conjunctival flap in the upper quadrants.
2. Create a limbal-based square (5x5 mm) or trapezoidal (5x5x2 mm) 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 EX-PRESS™ Delivery System, through that pre-incision.
7. Apply full depression of the EX-PRESS™ Delivery System digital detent button, allowing a smooth release of the EX-PRESS™ Glaucoma Filtration Device (Figure 4).
8. Release the EX-PRESS™ Delivery System detent button. The wire is permanently indented and fully retracted (single use only).
9. Withdraw the EX-PRESS™ Delivery System.
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.

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.
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