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DIRECTIONS FOR USE FOR THE XEN•45 GLAUCOMA TREATMENT SYSTEM

REF 5517-001 **AbbVie**

DEVICE DESCRIPTION

The XEN Glaucoma Gel Implant is intended to create a channel through the sclera allowing flow of aqueous humor from the anterior chamber into the subconjunctival space to reduce intraocular pressure (IOP). The XEN Gel Implant is inserted using the XEN Injector via an *ab interno* approach, through a small corneal incision.

The XEN Glaucoma Treatment System is comprised of the following sterile components:

- XEN Glaucoma Gel Implant; preloaded in XEN Injector

The XEN Glaucoma Treatment System is a sterile, single-use component. The XEN Injector is for single use only and is not reusable. Reuse may result in contamination, loss of function, and other undesirable side effects. Examine the packaging to verify the appropriate model has been selected and product has not expired prior to implantation.

MODEL DIMENSIONS

The XEN•45 Gel Implant has the following approximate dimensions.

XEN•45 Model	Length	Outside Diameter	Inside Diameter
5517-001	6 mm	150 µm	45 µm

XEN GEL IMPLANT

The XEN Gel Implant is composed of a gelatin derived from porcine dermis, formed into a tube, and then cross-linked with glutaraldehyde. The gelatin is designed to expand and become flexible when hydrated. The expansion of the tube's outer diameter also aids in retention of the Gel Implant in its intended location after surgical implantation.

XEN INJECTOR

The XEN Injector is a single use mechanical delivery system for the XEN Gel Implant. The Gel Implant is preloaded in the XEN Injector which houses the Gel Implant during insertion and delivery into the eye. The XEN Injector allows the surgeon to advance and deliver the Gel Implant to the desired location.

INDICATIONS

The XEN Gel Implant is intended to reduce intraocular pressure in patients with primary open angle glaucoma where previous medical treatments have failed.

CONTRAINDICATIONS

The XEN Gel Implant is contraindicated under the following circumstances or conditions: Angle closure glaucoma, previous glaucoma shunt/valve in the target quadrant, presence of conjunctival scarring, prior conjunctival surgery or other conjunctival pathologies (e.g., pterygium) in the target quadrant, active inflammation (e.g., blepharitis, conjunctivitis, keratitis, uveitis), active iris neovascularization or neovascularization of the iris within six months of the surgical date, anterior chamber intraocular lens, presence of intraocular silicone oil, vitreous present in the anterior chamber, impaired episcleral venous drainage (e.g., Sturge-Weber or nanophthalmos or other evidence of elevated venous pressure), known or suspected allergy or sensitivity to drugs required for the surgical procedure or any of the device components (e.g., porcine products or glutaraldehyde), history of dermatologic keloid formation.

ADVERSE EVENTS

Adverse events that may occur in conjunction with the use of the XEN Gel Implant include, but are not limited to localised or systemic allergic reaction, Gel Implant fracture, vision loss, corneal laceration/perforation, corneal decompensation, corneal edema, corneal endothelial cell loss, dellen formation, Descemet's membrane tear/detachment, cataract formation/progression, hypotony, IOP increase, secondary surgical interventions such as needling, Gel Implant migration, Gel Implant exposure or extrusion, Gel Implant blockage, wound leak, hypotony maculopathy, bleb related complications, choroidal effusion/haamorrhage/detachment, conjunctival perforation, conjunctivitis, eye injury, fibrosis, high intraocular pressure, inflammation/irritation, hyperaemia, toxic anterior segment syndrome (TASS), peripheral anterior synechiae, irido-corneal touch, iridocyclitis, iridialysis/iris rupture, iritis, iris atrophy, angle recession, cyclodialysis, lack of effectiveness, lacrimation, low intraocular pressure, malignant glaucoma, ocular pain, vision abnormalities, vascular occlusion, hypopyon, endophthalmitis, blebitis, ptosis and other known complications of intraocular surgery (e.g. dry eye, flat or shallow chamber, hyphema, macular edema, retinal detachment, vitreous hemorrhage, retinal haemorrhage, central or branch retinal vein occlusion, uveitis, as well as other infections and inflammatory conditions of ocular structures and surrounding tissues including but not limited to the cornea, sclera, uvea, iris, choroid, ciliary body, conjunctiva, and eyelid).

High IOP may result as a consequence of not following the directions for use.

Non-ocular specific symptoms of systemic infection, vomiting, and prion disease are rare events, that may be observed among patients implanted with the device.

WARNINGS/PRECAUTIONS

1. The XEN Gel Implant and Injector should be carefully examined in the operating room prior to use.
2. The patient's IOP should be monitored postoperatively. If the IOP is not adequately maintained after surgery, a therapeutic regimen or further intervention to reduce IOP should be considered.
3. In order to minimize trauma to the eye and associated complications, it is essential that the Gel Implant is placed in the proper subconjunctival location.
4. If increased resistance is observed at any time during the implantation procedure, stop the implantation procedure and use a new Injector.
5. To avoid the potential for implant damage (stent fracture or exposure), digital pressure following implantation of the XEN Gel Implant should be avoided.
6. The safety and effectiveness of the use of the XEN Gel Implant in neovascular, congenital and infantile glaucoma, or the use of more than one single implant at a time has not been studied.

DIRECTIONS FOR USE

1. **Remove XEN Injector from packaging**
   a. The XEN Injector is supplied preloaded and ready to use. After removing the injector from the tray, verify that the slider is in the full back position as shown in Figure 1. If the slider travel lock is absent or the slider of the XEN Injector has actuated, the Gel Implant could be potentially damaged, and should not be used.

Figure 1: Slider in full back position

2. **Remove needle cap and Gel Implant retention plug**
   a. The XEN Injector is shipped with a needle cap to protect the needle and a Gel Implant retention plug to ensure the XEN Gel Implant does not migrate out of the needle during shipping.
   b. Remove the needle cap.
   c. Remove the Gel Implant retention plug by grasping it lightly near the end of the plug and gently pull it away from the needle.
3. **Set Needle Bevel Angle Selector and remove slider travel lock**
   a. The XEN Injector has an adjustment for the angle of the needle bevel and can be adjusted to the desired position by moving the angle selector.
   b. Remove the yellow travel lock by grasping and pulling up.
4. **Perform surgery**

   The following description is not a replacement for surgeon training

   a. Standard ophthalmic surgery techniques are used to prepare the patient and the eye.
   b. Ophthalmic viscoelastic should be used to form the anterior chamber, as necessary. A secondary paracentesis may be made, if required, for injection of ophthalmic viscoelastic.
   c. The needle of the sterile XEN Injector preloaded with the XEN Gel Implant is advanced through the peripheral cornea and across the anterior chamber (i.e., ab interno) toward the targeted quadrant. Corneal entry should be at least 1 to 2 mm anterior to the limbus (i.e., not at the limbus or behind it) to ensure there is a proper angulation on the Gel Implant up and away from the iris. The Gel Implant should be placed through the centre of the angle.
   d. The needle's bevelled tip should be oriented upward as the needle is pushed through the trabecular meshwork (TM) and completely through the sclera. Gonioscopic guidance is recommended to be used to enter the TM. After the initial entry into the TM, gonioscopic guidance is no longer required to complete the scleral channel.
   e. Once the needle is aligned with the desired entry point in the anterior chamber angle, the surgeon should advance the needle in the anterior chamber angle and sclera until the surgeon is able to visualise the needle bevel as it exits the sclera into the subconjunctival space. Small adjustments forward or backward should be made to ensure the entire bevelled tip is visible in the subconjunctival space and the needle has relative freedom of movement within the sclera prior to releasing the XEN®45 Gel Stent.
   f. The surgeon initiates release of the XEN Gel Implant by moving the slider of the XEN Injector. To deploy the Gel Implant, a forward movement of the blue slider at the centre of the Injector delivers the Gel Implant and retracts the needle. The slider will stop at the end of its travel indicating that the procedure is complete.

g. Viscoelastic should be irrigated and aspirated from the anterior chamber using either low power or using a manual arrangement. Viscoelastic may be re-entered into the anterior chamber to maintain anterior chamber depth. Additionally, after closure of the conjunctiva and removal of the viscoelastic, a bleb should form.
h. Perform Seidel testing to ensure there is no leakage of aqueous from the anterior chamber or conjunctiva.

5. Discard

a. Upon completion of the surgery, discard the XEN Injector in a manner consistent with facility policy.

REPORTING

All adverse events that may be device related, regardless of the severity, must be reported to AbbVie.

HOW SUPPLIED

Each XEN Injector preloaded with the XEN Gel Implant is supplied sterile and non-pyrogenic in a tray sealed with a Tyvek lid. The sealed tray is placed in a unit box with labels and product information. The Gel Implant and Injector have been sterilized utilizing radiation.

EXPIRATION DATE

The expiration date on the device label is the sterility expiration date. In addition, there is a sterility expiration date clearly indicated on the outside of the unit box. Sterility is assured until the expiration date if the tray and Tyvek lid are not punctured or damaged and the seal is not compromised. This device should not be used past the indicated sterility expiration date.

RETURN GOODS POLICY

Product returns or exhanges must be authorized through your AbbVie representative. For more information, please contact your AbbVie representative.

Symbol	English	Symbol	English	Symbol	English
	Caution: Read Instructions for Use Prior to Use		Use By (YYYY-MM)		Catalog / Model Number
	Sterilized using Irradiation (Gamma)		Serial Number		Do Not Use If Package Is Damaged
	Manufacturer		Do Not Reuse		Lot Number

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