DIRECTIONS FOR USE FOR THE XEN•45 GLAUCOMA TREATMENT SYSTEM

REF 5507-001 **AqueSys, Inc.**

DEVICE DESCRIPTION

The AqueSys XEN Gel Stent 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 Stent is inserted using the XEN Injector via an *ab interno* approach, through a small corneal incision.

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

- XEN Gel Stent; 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 Stent has the following approximate dimensions.

XEN•45 Model	Length	Outside Diameter	Inside Diameter
5507-001	6 mm	150 µm	45 µm

AQUESYS XEN GEL STENT

The XEN Gel Stent 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 Stent in its intended location after surgical implantation.

AQUESYS XEN INJECTOR

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

INDICATIONS

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

CONTRAINDICATIONS

The AqueSys XEN Gel Stent 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.

WARNINGS

The following may occur in conjunction with the use of the AqueSys XEN Gel Stent: Gel Stent migration, Gel Stent exposure or extrusion, Gel Stent blockage, choroidal effusion or hemorrhage, hypotony maculopathy, bleb related complications, or endophthalmitis and other known complications of intraocular surgery (e.g., flat or shallow chamber, hyphema, corneal edema, macular edema, retinal detachment, vitreous hemorrhage, uveitis).

PRECAUTIONS

1. The XEN Gel Stent 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 Stent is placed in the proper subconjunctival location.

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 Stent could be potentially damaged, and should not be used.

Figure 1: Slider in full back position

2. **Remove needle cap and Gel Stent retention plug**
   a. The XEN Injector is shipped with a needle cap to protect the needle and a Gel Stent retention plug to ensure the XEN Gel Stent does not migrate out of the needle during shipping.
   b. Remove the needle cap.
   c. Remove the Gel Stent 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. The needle of the sterile XEN Injector preloaded with the XEN Gel Stent 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 Stent up and away from the iris. The Gel Stent should be placed through the center of the angle.
   c. Once the needle is aligned with the desired entry point in the anterior chamber angle, the surgeon advances the needle in the anterior chamber angle and sclera until the surgeon is able to visualize the needle bevel as it exits the sclera into the subconjunctival space.
   d. The surgeon initiates release of the AqueSys XEN Gel Stent by moving the slider of the XEN Injector. To deploy the Gel Stent, a forward movement of the blue slider at the center of the Injector delivers the Gel Stent and retracts the needle. The slider will stop at the end of its travel indicating that the procedure is complete.
5. **Discard**
   a. Upon completion of the surgery, discard the XEN Injector in a manner consistent with facility policy.

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as device related and not previously expected in nature, severity or incidence must be reported to AqueSys, Inc. or their representative via telephone or fax at the numbers listed below.

HOW SUPPLIED

Each XEN Injector preloaded with the XEN Get Stent 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 Stent 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

Contact AqueSys, Inc. or their representative via telephone or via fax at the numbers listed below.

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
	European Union Authorized Representative				


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