



DIRECTIONS FOR USE FOR THE XEN® GLAUCOMA TREATMENT SYSTEM

MODEL # 5513-001: XEN® GLAUCOMA TREATMENT SYSTEM

DEVICE DESCRIPTION

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

- XEN®45 Gel Stent; preloaded into a
- XEN® Injector

The XEN®45 Gel Stent is a glaucoma implant designed to reduce intraocular pressure in eyes suffering from refractory glaucoma. The device creates a permanent channel through the sclera allowing flow of aqueous humor from the anterior chamber into the subconjunctival space. The XEN®45 Gel Stent is inserted using the XEN® Injector via an *ab interno* approach, through a small corneal incision.

The XEN® Injector is sterile and for single use only. Reuse may result in contamination, loss of function, and other undesirable side effects.

XEN®45 GEL STENT

The XEN®45 Gel Stent is composed of a gelatin derived from porcine dermis, formed into a tube, and then cross-linked with glutaraldehyde. The durable gelatin is designed to minimally swell, soften, and become flexible when hydrated. The stent's design also aids in retention of the XEN®45 Gel Stent in its intended location after surgical implantation.

The XEN®45 Gel Stent dimensions (approximations) for the dry state are shown in **Table 1**:

Table 1
XEN®45 Gel Stent Dimensions

XEN®45 Gel Stent Measurements	Dry Dimensions
Length	6 mm
Inner Diameter	45 µm
Outer Diameter	150 µm

XEN® INJECTOR

The XEN® Injector is a single-use mechanical delivery system for the XEN®45 Gel Stent, which is preloaded in the XEN® Injector for insertion and delivery into the eye. The XEN® Injector allows the surgeon to advance and deliver the XEN®45 Gel Stent to the desired location.

INDICATIONS

The XEN® Glaucoma Treatment System is indicated for the management of refractory glaucomas, including cases where previous surgical treatment has failed, cases of primary open angle glaucoma, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy.

CONTRAINDICATIONS

Implantation of the XEN®45 Gel Stent is contraindicated under the following circumstances or conditions:

- Angle closure glaucoma where angle has not been surgically opened
- 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

WARNINGS

The complications that may occur in conjunction with the use of the XEN®45 Gel Stent include, but are not limited to, choroidal effusion, hyphema, hypotony, implant migration, implant exposure, wound leak, need for secondary surgical intervention and other known complications of intraocular surgery (e.g., flat or shallow chamber, corneal edema, endophthalmitis).

The safety and effectiveness of this device in neovascular, congenital and infantile glaucoma has not been established.

To avoid the potential for implant damage (stent fracture or exposure), digital pressure following implantation of the XEN®45 Gel Stent should be avoided.

PRECAUTIONS

1. The XEN®45 Gel Stent and XEN® 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. If increased resistance is observed at any time during the implantation procedure, stop the implantation procedure immediately and use a new XEN® system.
4. The safety and effectiveness of more than a single implanted XEN®45 Gel Stent has not been studied.

DIRECTIONS FOR USE

The XEN®45 Gel Stent is intended for placement through a clear corneal incision after the implantation site has been confirmed through adequate visualization of the anterior chamber angle.

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.

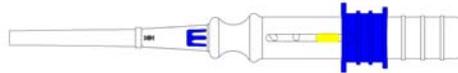


Figure 1: Slider in full back position

2. Remove needle cap and retention plug
 - a. The XEN[®] Injector is shipped with a needle cap to protect the needle and a retention plug to ensure the XEN[®]45 Gel Stent does not migrate out of the needle during shipping.
 - b. Remove the needle cap.
 - c. Remove the 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 should be 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 by the investigator, for injection of ophthalmic viscoelastic.
 - c. Apply sponges saturated with Mitomycin C (0.2 mg/ml) to the surgical site for 2 minutes. Remove sponges from the eye and copiously irrigate the surgical site.
 - d. The needle of the sterile XEN[®] Injector preloaded with the XEN[®]45 Gel Stent is advanced through the peripheral cornea and across the anterior chamber (i.e., the *ab interno* approach) 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 XEN[®]45 Gel Stent up and away from the iris. The XEN[®]45 Gel Stent should be placed through the center of the angle.
 - e. The needle's beveled tip should be oriented upward as the needle is pushed through the trabecular meshwork (TM) and completely through the sclera. Gonioscopic guidance should be used to enter the TM. After the initial entry into the TM, gonioscopic guidance is no longer required to complete the scleral channel.
 - f. The patient's eye will need to be stabilized during the needle advancement through the sclera. Therefore, to stabilize the eye, it is recommended to grasp the cornea at the primary or a secondary paracentesis with a set of forceps, or an alternative instrument deemed appropriate to provide sufficient counterforce in the opposite direction of the implanting needle while the needle is being advanced through the sclera.
 - g. 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 visualize the needle bevel as it exits the sclera into the subconjunctival space. Small adjustments forward or backward should be made to ensure the entire beveled 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.
 - h. The eye should be allowed to relax and release any torsion or counterforce and to assume a natural posture prior to releasing the XEN[®]45 Gel Stent.
 - i. The surgeon should initiate release of the XEN[®]45 Gel Stent by moving the slider of the XEN[®] Injector. To deploy the XEN[®]45 Gel Stent, a forward movement of the blue slider at the center of the injector delivers the XEN[®]45 Gel Stent and retracts the needle. The slider will stop at the end of its travel indicating that the procedure is complete. The injector will deploy the XEN[®]45 Gel Stent approximately 2 mm into the subconjunctival space.
 - j. A properly placed XEN[®]45 Gel Stent will have approximately 1 mm visible in the anterior chamber and approximately 2 mm visible in the subconjunctival space. The exit from the sclera should be approximately 3 mm from the limbus. A XEN[®]45 Gel Stent that has a visible end in the anterior chamber and a visible end in the subconjunctival space should be considered properly implanted.
 - k. Close the conjunctiva using a 10-0 Vicryl or nylon suture.
 - l. 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.
 - m. Perform Seidel testing to ensure there is no leakage of aqueous from the anterior chamber or conjunctiva.
 - n. Should the final position of the XEN[®]45 Gel Stent not be in the correct location (e.g., if the stent extends too far into the anterior chamber), the device may be exchanged. To exchange the device, grasp it near the point where it enters the angle. Gently pull the device away from the angle. Once you feel the stent move, release it and then grasp it again near the point where it enters the angle. Repeat this process until the stent is completely within the anterior chamber and can be removed through the corneal incision. The replacement stent should be implanted in the same quadrant or as near as possible to the original location of the removed stent using the same technique as implantation of the initial stent.
 - o. If the XEN[®]45 Gel Stent is positioned too far into the subconjunctival space, remove it through a small conjunctival incision using forceps.
 - p. If required, bleb needling is recommended to be performed in the operating room. Use caution during the needling procedure to avoid direct contact with and damage of the XEN[®]45 Gel Stent.

CLINICAL TRIAL

A prospective, multi-center, single arm, open-label, clinical trial was conducted at 12 sites in the U.S. to evaluate the safety and effectiveness of the XEN[®]45 Gel Stent in refractory glaucoma subjects where previous filtering or cilioablativ procedures failed or IOP was unresponsive to maximally tolerated medical therapy. Sixty-five subjects were implanted with the XEN[®]45 Gel Stent and 18-month data were collected for safety.

In this clinical investigation, a topical antibiotic was started at least 1 day prior to surgery and continued 1 week following the surgery. In addition, a topical steroid was started 5-7 days prior to surgery at the discretion of the surgeon and continued through a 12 week taper also at the discretion of the surgeon. A commercially available wound treating agent (Mitosol[®] mitomycin for solution; 0.2 mg/vial) was applied preoperatively in accordance with its approved prescribing information.

Demographics and Baseline Characteristics

The mean age of subjects was 70.0 years and there were 30 males (46.2%) and 35 females (53.8%). Thirty-eight (58.5%) subjects were White, 13 (20.0%) were Hispanic or Latino, 11 (16.9%) were Black/African American, and three (4.6%) were Asian. Fifty-seven subjects were diagnosed with primary open angle glaucoma (POAG), six subjects had pseudoexfoliative glaucoma, one subject had pigmentary glaucoma, and one subject had mixed mechanism glaucoma. Most subjects (45; 69.2%) had prior cataract surgery, 41 (63.1%) had a prior incisional glaucoma procedure (e.g., trabeculectomy, tube shunt,

canaloplasty, trabeculotomy, AquaFlow), 14 (21.5%) had undergone prior laser trabeculoplasty without an incisional glaucoma procedure, and 10 (15.4%) had no prior glaucoma procedures and were not responsive to maximally tolerated medical therapy. In addition to having refractory glaucoma, they also had advanced disease with a mean cup-to-disc ratio of 0.8 and a mean visual field mean deviation (MD) score of -15 dB.

The mean medicated IOP at baseline was 25.1 (± 3.7) mmHg and subjects were using a mean of 3.5 (± 1.0) IOP-lowering medications at baseline.

Complications and Adverse Events

There were no intraoperative or surgical complications as shown in **Table 2**.

Table 2
Intraoperative Surgical Complications
XEN® Implanted Subjects
(N = 65)

Events	# of Subjects	% of Subjects
No surgical complication	65	100%
Detached Descemet's membrane	0	0%
Iris damage	0	0%
Lens contact	0	0%
Vitreous bulge or loss	0	0%
Hyphema	0	0%
Retrolubar hemorrhage	0	0%
Conjunctival perforation	0	0%
Shallow anterior chamber with peripheral iridocorneal touch	0	0%
Flat anterior chamber with iridocorneal touch extending to the pupil	0	0%
Device malfunction identified prior to implantation	0	0%
Choroidal hemorrhage or effusion	0	0%

Operative parameters are shown in **Table 3**. For the majority of subjects (N=56, 86.2%) only one injector was used to implant the XEN®45 Gel Stent. Nine subjects (13.8%) required intraoperative stent removal and replacement with 11 devices in order to ensure proper placement (i.e., due to too much length in the anterior chamber) of the XEN®45 Gel Stent.

Table 3
Operative Parameters
XEN® Implanted Subjects

Parameter	N = 65 n (%)
Stent Implanted	
Yes	65 (100%)
No	0 (0%)
Implant Location	
Superior nasal	56 (86.2%)
Superior temporal	9 (13.8%)
Number of Injectors Used Per Subject	
1	56 (86.2%)
2	6 (9.2%)
3	3 (4.6%) ¹
Intraoperative Stent Removal and Replacement	
No	56 (86.2%)
Yes	9 subjects (13.8%)/11 events
Operative Device Malposition	9 subjects (13.8%)/11 events
Operative Device Obstruction	0 (0%)
Injector Misfires	0 (0%)
% = $n \div N \times 100$	

¹ Although 3 injectors were used for 3 subjects; only 2 subjects had 2 intraoperative replacements. For one injector, the gel stent was lost prior to implantation and therefore an intraoperative replacement was not performed.

Subject Accountability

Fifty-four subjects (83.1%) completed the 12-month visit and 49 subjects (75.4%) completed the 18-month visit.

Postoperative Events

Table 4 summarizes the postoperative adverse events reported during the course of the pivotal clinical study through the 12-month visit. There have been no reports of migration, exposure, hypotony, endophthalmitis, or unanticipated events reported after the 12-month visit in the 53 subjects who were seen after the 12-month visit.

Table 4
Ocular Adverse Events
(N = 65)

Events	N=65 N (%)
Angle recession	0 (0%)
Anterior chamber shallow with peripheral irido-corneal touch	1 (1.5%)
Anterior chamber flat with irido-corneal touch	0 (0%)
BCVA loss of ≥ 2 lines (≥ 10 ETDRS letters) ¹	
≤ 30 days ²	10 (15.4%)
> 30 days	7 (10.8%)
At 12 months (persistent loss) ³	4 (6.2%)
Bleb leak (without operative room or slit lamp revision)	1 (1.5%)
Bleb leak (with operative room or slit lamp revision)	0 (0%)
Blebitis (with or without anterior chamber reaction or hypopyon)	0 (0%)
Cataract formation	0 (0%)
Cataract worsening of 2.0 or more on LOCS III at 2 or more visits ⁴	0 (0%)
Choroidal effusion (extending posterior to equator, without blood)	2 (3.1%)
Choroidal effusion (obscuring disc or macula, without blood)	0 (0%)
Choroidal effusion (with choroids touching in the center of the eye, without blood)	0 (0%)
Choroidal effusion (extending posterior to equator, with blood)	0 (0%)
Choroidal effusion (obscuring disc or macula, with blood)	0 (0%)
Choroidal effusion (with choroids touching in the center of the eye, with blood)	0 (0%)
Choroidal effusion and/or hemorrhage occurring > 30 days (persistent)	0 (0%)
Chronic pain (present greater than 3 months)	0 (0%)
Corneal edema grade 3 or grade 4 (> 30 days postoperatively)	1 (1.5%)
Cyclodialysis	0 (0%)
Dellen	1 (1.5%)
Device malfunction	0 (0%)
Endophthalmitis	0 (0%)
HypHEMA (≥ 2 mm in height (layered) at any time)	3 (4.6%)
HypHEMA (present or arising > 30 days)	0 (0%)
Hypotony (IOP < 6 mmHg at any time)	16 (24.6%) ⁵
Persistent hypotony (IOP < 6 mmHg at two visits > 30 days apart)	0 (0%) ⁵
Hypotony maculopathy	0 (0%)
Implant exposure	1 (1.5%)
Implant fracture	0 (0%)
Implant migration	1 (1.5%)
Implant obstruction (complete or partial)	0 (0%)
Implant repositioning requiring surgical intervention	1 (1.5%)
Increase in C/D ratio of ≥ 0.3 units on slit lamp examination	0 (0%)
Increase in corneal thickness of $\geq 10\%$ in the presence of corneal edema	0 (0%)
IOP increase ≥ 10 mmHg from baseline	14 (21.5%) ⁶
Iridodialysis	0 (0%)
Iritis (requiring treatment after the postoperative medication taper)	0 (0%)
Loss of eye	0 (0%)
Macular edema	1 (1.5%)
Needling procedure ⁷	21 (32.3%) ⁸
Ptosis	0 (0%)
Retinal complications	0 (0%)
Secondary surgical intervention⁶	
Explant	1 (1.5%)
Secondary glaucoma procedure with explant	6 (9.2%)
Secondary glaucoma procedure	2 (3.1%)
Significant (2-grade) worsening or a grade of moderate or severe, for any slit lamp observation for which a standard grading scale is not available (> 30 days postoperatively)	
Anterior chamber cells	2 (3.1%)
Blepharitis	1 (1.5%)
Chalazion	1 (1.5%)
Dysesthetic bleb	1 (1.5%)
Hyperemia	1 (1.5%)
Significant iris injury or atrophy	0 (0%)
Strabismus	0 (0%)
Suture abscess or other local infection	0 (0%)
Vitreous hemorrhage	0 (0%)
Wound leak/dehiscence	6 (9.2%)

Events	N=65 N (%)
Other AE	
Anterior chamber fill	1 (1.5%)
Anterior chamber tap	6 (9.2%)
Fixed dilated pupil	1 (1.5%)
Macular puckering	1 (1.5%)
Vitreous loss ⁹	1 (1.5%)
Wound repair	5 (7.7%)
YAG capsulotomy	3 (4.6%)

¹ No subjects experienced loss of light perception

² Includes data reported ≤ 30 days or reported at the 1-month visit

³ Persistent BCVA loss was attributed to cataract formation with subsequent cataract surgery after the 12-month visit (1 subject); loss of visual field and macula changes (1 subject); macular puckering (1 subject); and unknown etiology (1 subject).

⁴ Although not meeting the criteria of 2.0 or more on LOCS III grading system at two or more visits, one subject experienced a cataract worsening from NO2.5 to NO3.0 at the 8-month visit and subsequently underwent cataract surgery after the 12-month visit

⁵ The protocol defined any occurrence of IOP < 6 mmHg as an adverse event, regardless of whether there were any associated complications or sequelae related to the low pressure. No clinically significant consequences were associated with these hypotony cases such as choroidal effusions, suprachoroidal hemorrhage or hypotony maculopathy. Thirteen cases occurred at the 1-day visit; there were no cases of persistent hypotony and no surgical intervention was required for any case of hypotony.

⁶ Of the 14 subjects with IOP increase ≥ 10 mmHg from baseline, six subjects had a secondary glaucoma procedure and/or device explant prior to the 12-month visit.

⁷ Includes needling procedures performed with and without antimetabolites

⁸ In the American Academy of Ophthalmology's (AAO) Preferred Practice Patterns for Primary Open Angle Glaucoma, bleb needling is listed as a recommended action "as necessary" in the perioperative care in glaucoma surgery to maximize the chances for successful long-term results.

⁹ Slit lamp observation of trace vitreous in the anterior chamber was noted in one subject at the 1-week visit and was observed through the postoperative period. No intervention was performed and the subject remained stable with no complications related to this finding.

Table 5 summarizes the bleb needling procedures performed through the 12-month visit.

Table 5
Bleb Needling Procedure at ≤ 12 Months
XEN[®] Implanted Subjects

	N = 65 n (%)
Bleb Needling Performed	
Yes	21 (32.3%)
No	44 (67.7%)
Reason for Bleb Needling¹	
Flat bleb with absence of microcysts	11 (16.9%)
Bleb filtration area is fibrotic or blocked	12 (18.5%)
Subject has a high risk of bleb failure based on assessment by the investigator	10 (15.4%)
Number of Needling Procedures Performed per Subject	
1	14 (21.5%)
2	6 (9.2%)
3	1 (1.5%)
# of Subjects who had Needling Procedure with MMC	
No	14 (21.5%)
Yes	7 (10.8%)

% = $n \div N \times 100$

¹ More than one reason could be reported for the same needling procedure

Effectiveness

The XEN[®] Glaucoma Treatment System is effective in reducing intraocular pressure in a refractory glaucoma population. In this clinical investigation a medication washout was not performed; all IOP-lowering medications were discontinued on the day of surgery. The medicated baseline IOP for the XEN[®]45 Gel Stent subjects was 25.1 (± 3.7) mmHg and the 12-month mean IOP for the XEN[®]45 Gel Stent population was 15.9 (± 5.2) mmHg for the subjects who completed the 12-month visit (n=52). The mean baseline number of IOP-lowering medications was 3.5 (± 1.0) as compared to the 12-month results where the 52 subjects who completed the 12-month visit were using on average 1.7 (± 1.5) medications.

Tables 6 and 7 provide an overview of the primary effectiveness analyses based on 12-month diurnal IOP data. Sixty-five subjects received the XEN[®]45 Gel Stent. Prior to the 12-month visit, two subjects died and two subjects were considered lost to follow-up resulting in 61 subjects available for the overall effectiveness analyses (observed data, without the use of imputed data).

Table 6
Effectiveness Analyses
% of Subjects with 12-Month Mean Diurnal IOP Reduction
of ≥ 20% from Baseline on Same or Fewer Medications
(N=65)

Analysis Population¹	n/N (%) (95% CI)¹
Effectiveness Analysis Using Observed Data & Failure for Glaucoma-Related Secondary Surgical Intervention & Failure Assumption for Missing Data (N=65) ²	46/65 (70.8%) (58.2%, 81.4%)
Effectiveness Analysis Using Observed Data & Failures for Glaucoma-Related Secondary Surgical Intervention (N=61) ³	46/61 (75.4%) (62.7%, 85.5%)
Effectiveness Analysis Using Observed Data & Failures for subjects with Glaucoma-Related Secondary Surgical Intervention & Multiple imputations for Missing Data (Primary Analysis for N=65)	76.3% (65.8%, 86.8%)

Study eyes undergoing glaucoma-related secondary surgical intervention and/or removal of the XEN®45 Gel Stent prior to the 12-month evaluation were considered to be non-responders.

7 subjects in the study underwent needling procedures with MMC; 4 of these subjects were considered responders.

¹ Exact confidence limits per Clopper-Pearson method

² 4 subjects who missed the 12-month visit (2 due to death and 2 due to lost to follow-up) were considered non-responders

³ 4 subjects who missed the 12-month visit (2 due to death and 2 due to lost to follow-up) were excluded from the total cohort

Table 7
Effectiveness Analyses of
Mean Diurnal IOP Reduction from Baseline at the 12-Month Visit
(N=65)

Analysis Population¹	Mean ± SD (95% CI)¹
Effectiveness Analysis Using Observed Data & Worst within-eye IOP for subjects with Glaucoma-Related Secondary Surgical Intervention & Worst within-eye IOP for Missing Data (N=65) ²	-5.8 ± 9.0 (-8.0, -3.5)
Effectiveness Analysis Using Observed Data & Worst within-eye IOP for subjects with Glaucoma-Related Secondary Surgical Intervention (N=61) ³	-6.2 ± 9.1 (-8.5, -3.9)
Effectiveness Analysis Using Observed Data & Worst within-eye IOP for subjects with Glaucoma-Related Secondary Surgical Intervention & Multiple imputations for Missing Data (Primary Analysis for N=65)	-6.4 ± 1.1 ⁴ (-8.7, -4.2)

Study eyes undergoing glaucoma-related secondary surgical intervention and/or removal of the XEN®45 Gel Stent prior to the 12-month evaluation were considered to be non-responders. The within-eye worst value was used for the analysis for these eyes.

7 subjects in the study underwent needling procedures with MMC; 4 of these subjects were considered responders.

¹ Based on t-distribution

² 4 subjects who missed the 12-month visit (2 due to death and 2 due to lost to follow-up) were considered non-responders; the within-eye worst value was used for the analysis for these eyes

³ 4 subjects who missed the 12-month visit (2 due to death and 2 due to lost to follow-up) were excluded from the total cohort

⁴ Mean ± SE for this value

Table 8 provides a summary of those subjects who were non-responders at the 12-month visit.

Table 8
Subjects who were Non-Responders at 12 Months

Reason for being a non-responder	N = 65 n (%)
Did not achieve 12-month mean diurnal IOP reduction of ≥ 20% compared to baseline IOP on the same or fewer number of medications ¹	6 (9.2%)
Secondary glaucoma surgery with device explant prior to 12 months	6 (9.2%)
Secondary glaucoma surgery (no device explant) prior to 12 months	2 (3.1%)
Device explant prior to 12 months	1 (1.5%)
Number of medications used at 12 months exceeded the number of medications used at baseline	0 (0%) ²
Subject missed 12-month visit	4 (6.2%) ³

¹ Fixed-combination medications (i.e., Combigan, Cosopt, Simbrinza) at baseline or at the 12-month visit, the medications were counted as two IOP-lowering medications.

² No subjects were taking oral IOP-lowering medications at the 12-month visit.

³ 4 subjects missed the 12-month visit (2 due to death and 2 due to lost to follow-up).

ADVERSE EVENT 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 Allergan, Inc. in the US at 1-800-624-4261.

HOW SUPPLIED

Each XEN® Injector preloaded with the XEN®45 Gel 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 gamma irradiation.

STORAGE

Store at room/ambient temperature.

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 exchanges must be authorized through your Allergan representative. For more information, please contact your Allergan representative.

Rx Only

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

Manufactured By:
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612

XEN® is a registered trademark of AqueSys, Inc., an Allergan affiliate.

Patents 6,007,511; 8,663,303; 8,721,702; 8,765,210; 8,852,136; 8,852,256; 9,017,276; 9,192,516; 9,095,413; 9,113,994.
Additional patents for the Gel Stent, Injector and procedure are pending.