XEN® 45 Glaucoma Treatment System – 5507-001

Australian/New Zealand SKU number 5517-001

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Intended Purpose / Indication

The XEN® Glaucoma Treatment System is intended to reduce intraocular pressure in patients with primary open angle glaucoma where previous medical treatments have failed.

Glaucoma is a complex eye disease that can damage the optic nerve and cause progressive, irreversible vision loss. In the most common forms of glaucoma, there is an increase of pressure inside the eye. When previous treatment has failed to reduce the pressure inside the eye, this is called refractory glaucoma. An abnormal increase in pressure inside the eye occurs when fluid does not drain properly.

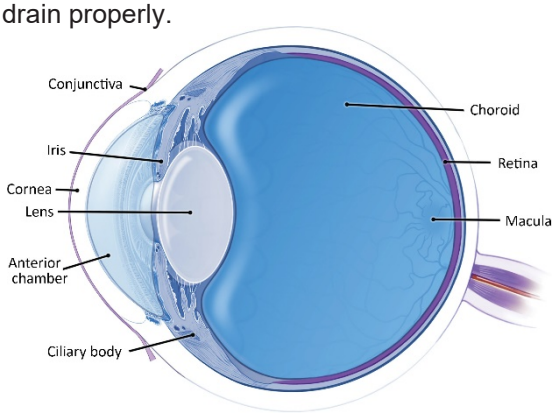

Figure 1: Eye Anatomy Referred to in this Leaflet

Open angle glaucoma, which is the form that affects 90% of glaucoma patients is caused by the gradual obstruction of the drainage channels inside the eye. This causes eye pressure to increase. Vision loss may occur when eye pressure becomes too high and damages the optic nerve.

When your doctor implants a XEN® Gel Implant, in essence they are making a new drainage channel so fluid from the inside of the eye can be directed to the outside of the eye, thus relieving pressure. The tissue that forms a fluid reservoir over this surgically created drainage channel is called a “bleb.”

Patient Population

The XEN® Glaucoma Treatment System is implanted in patients with primary open angle glaucoma where previous medical treatments have failed.

Intended Performance
The XEN® Gel Implant creates a small channel in the eye to drain fluid and help lower eye pressure. The XEN® Gel Implant is tiny – about the length of an eyelash – and it's placed just under the conjunctiva, which is a clear membrane that covers the white of your eye.

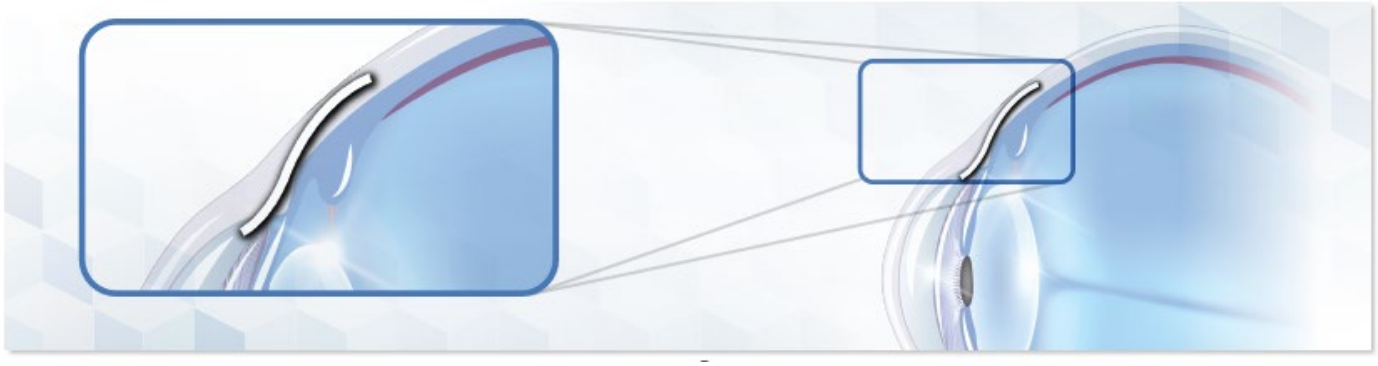

Figure 2: Position of the XEN® Gel Implant within the Eye

Side Effects
Side effects after surgery may include worsening vision or visual loss, visual distortions, too low eye pressure, too high eye pressure and worsening of current glaucoma. You may experience the sensation of a foreign body in your eye. You may have an allergic reaction to the XEN® Gel Implant.The choroid (inner layer of blood vessels) or other areas of the eye may bleed or detach (separate). Infection and inflammation and/ or irritation in the eye may occur. Scarring or complications due to scarring in the eye may occur. Swelling of structures in the eye may occur.

One or more parts of your eye may become infected.

The conjunctiva (thin tissue layer that covers the eye) may bleed, break or tear. The bleb (an elevated area of tissue on the surface of the eye where the fluid that is leaving the eye gets collected) may flatten, leak, or become too thin.

Connective tissue in your eye may thicken.

You may find you make tears more often. You may experience pain in your eye.

The cornea is a transparent layer that covers the pupil (the opening at the center of the eye), iris (the coloured part of the eye), and anterior chamber (the fluid-filled inside of the eye). The cornea may become scratched, perforated, or torn. The cornea may swell, lose cells, become opaque, swell, or develop a sore. Small depressions may develop in your cornea. Blood may accumulate in your anterior chamber. The anterior chamber may flatten or become shallow.

The ciliary body is a structure just behind the iris, and it changes the shape of your lens when you focus on a near object. The ciliary body may detach from the sclera (white outer layer of the eyeball) or it may tear.

A cataract (cloudiness in your lens) may form.

The retina is the light-sensitive area that lines the inner surface of the eye. The retina may detach, tear, or the veins in it may become blocked or closed. The macula is an area in the center of the retina. Fluid may build up in the macula and cause visual distortions.

Your XEN® Gel Implant may become blocked, break, tear, or otherwise become damaged. XEN implant movement, XEN malposition (incorrect placement), or exposure of XEN to the outside may occur.

Warnings

Not all glaucoma patients are suitable candidates to receive the XEN® Gel Implant. If you have any concerns or questions, please speak with your doctor.

XEN® Gel Implant complications may include buildup of fluid between the choroid and the sclera, blood in the eye, very low eye pressure, implant moving to another part of the eye, implant exposure, wound leak, need for additional surgical intervention, and other eye surgery complications. The safety and effectiveness of the XEN® Glaucoma Treatment System in neovascular (glaucoma from the creation of new blood vessels in the eye), congenital (glaucoma present at

birth), and infantile (glaucoma that develops 1 – 24 months after birth) glaucoma has not been established.

Precautions
Your doctor should check and manage your eye pressure appropriately. The safety and effectiveness of implanting more than one XEN® Gel Implant in an eye has not been studied.

Contact your doctor immediately if you notice a change in vision, light sensitivity, pain, redness, and/or swelling in the eye that has the XEN® implant.

Maintenance and Monitoring
Your doctor should check and manage your eye pressure appropriately. Please follow all your doctor's instructions.

After the XEN® Glaucoma Treatment System procedure, to help avoid the possibility of implant damage, movement, or infection, avoid rubbing, touching or pressing your fingers on the eye in the area where the XEN® Gel Implant was implanted.

Compatibility
The XEN® Gel Implant does not interact with other medical and/or electrical equipment and is compatible with magnetic resonance imaging.

Device Lifetime
The XEN® Gel Implant is intended to be a permanent implant. Please follow all your doctor's instructions after XEN® implantation.

Materials
The XEN® Gel Implant is composed of a porcine-derived gelatin, formed into a tube, and then bonded to glutaraldehyde to maintain its shape and durability. The finished tube is approximately 0.220 mm around, 6 mm long, and weighs 0.000215 grams. The XEN® Gel Implant does not contain any manufacturing residuals that can pose a risk to patients.

Reporting
If you experience any serious incidents related to your XEN® Glaucoma Treatment System, report them to AbbVie and to the Therapeutic Goods Administration at https://www.tga.gov.au.

Adverse events should be reported to your local AbbVie office, Australia 1800 252 224 or New Zealand 0800 659 912.

Symbols:
The following symbols are used on the patient implant card:

The XEN® Glaucoma Treatment System model number.

The date after which the XEN® Glaucoma Treatment System was not to be implanted.

The XEN® Glaucoma Treatment System's serial number – a number unique to this particular Gel Implant.

The XEN® Glaucoma Treatment System lot number – a number that identifies a manufacturing batch of system.

Caution

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