

Ophthalmology Department

XEN Gel Stent for Open Angle Glaucoma

What is the XEN Gel Stent?

The XEN Gel Stent is a new, less invasive surgical procedure used to treat glaucoma. A tiny stent is placed in your eye to create a permanent pathway to increase drainage of fluid out of your eye. This helps preserve your vision by reducing the pressure in your eye.

The stent is a soft implant about 6mm long and about the width of a human hair. It is placed through a small (approximately 1.9mm), incision in the cornea (front clear window of the eye). It is implanted from a preloaded injector with a fine needle. Mainly an internal approach is used to place it and it comes out above the sclera (white of the eye) in the upper nasal quadrant. It drains fluid from within the eye to a low profile fluid lake which gets absorbed in the blood vessels of the eye.

The XEN Gel Stent is made from soft, collagen derived gelatin material of porcine (pig) origin. It will not set off airport scanners and will not cause any problems if you need to have an MRI scan.

What are the benefits of XEN Gel Stent?

XEN Gel Stent aims to lower your eye pressure to try and prevent your glaucoma from getting worse. It is not aimed at improving your vision. In some cases it may reduce the need to use eye drops for glaucoma.



How is this procedure different from other glaucoma surgery?

The XEN stent implantation procedure is different from conventional glaucoma surgery in the following ways:

- **Mechanics:** the procedure involves a microscopic device instead of major surgical alteration of your own tissues to maintain opening for fluid flow.
- **Invasiveness of surgery:** this surgery is much less invasive than the conventional surgical procedure
- **Type of surgery:** device implantation is mainly by an internal approach instead of **external** creation of a drainage channel – this aims to reduce chances of scarring on the surface of the eye which could make further glaucoma surgery more difficult. The surgeon may combine this with a limited external approach to apply adjunctive medications to improve efficacy and/or safety of the procedure.

Is the XEN Gel Stent suitable for everyone?

XEN Gel Stent is suitable for patients who have an open drainage angle so that the surgeon can implant the device. It is not suitable for all patients with glaucoma.

It may be used in conjunction with cataract surgery, after or before cataract surgery. Your doctor will discuss and explain the suitability of the XEN Gel Stent with you.

Will the XEN Gel Stent cure my glaucoma?

XEN Gel Stent aims to prevent your glaucoma from getting worse by lowering your eye pressure.

As with all other glaucoma treatments, it cannot cure glaucoma. It can neither reverse any damage already caused by glaucoma nor bring back any lost vision.

What are the risks and complications of XEN Gel Stent?

XEN Gel Stent is a relatively new procedure. The initial information is very encouraging but there is not a lot of information yet about its efficacy and long term benefits. Based on the available clinical trial results it is only being offered to those patients who are particularly suitable or where alternative options carry a higher potential risk of complications. We shall be continually examining the outcomes for patients who have the implant.

The XEN implant procedure is designed to be less traumatic than conventional glaucoma surgery (Trabeculectomy), and therefore damage to eye structures is expected to be less than conventional surgery

Potential complications include:

Infection

Infection can happen after any eye operation. Usually the risk of severe infection causing loss of vision is considered to be about 1 in 500. You will be given antibiotic eye drops to use after the operation to reduce the risk of the eye developing an infection.

As an implant is being put in the eye and a drainage area (bleb) is being created, there is a long-term increased risk of infection. If you subsequently develop a red, sticky or painful eye, it is important to have your eye examined immediately by an ophthalmologist, as this may be a sign of an infection.

Bleeding

The eye does not like sudden changes in pressure and this can cause a sudden bleed in the eye. Steps are taken to prevent a sudden drop of pressure during the operation and severe bleeding in the eye is very uncommon.

Inflammation

All eye operations lead to some inflammation. Usually this is controlled by the medications given after the operation. It can be severe and may require prolonged treatment, but this is uncommon

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High pressure after surgery

Sometimes the pressure may remain high after surgery if the implant does not help drainage or if the healing response of the body limits it. This is usually controlled with pressure lowering drops and additional procedures to control the pressure may need to be explored.

Low pressure after surgery

Sometimes the pressure may be too low after surgery. This is usually detected during clinic appointments and is often remedied by stopping any pressure-lowering eye drops and reducing steroid eye drops. Sometimes an injection of viscoelastic (a jelly like material) in the front chamber of the eye is required to raise the pressure. Although very low pressure is often painless, it may be associated with a dull aching feeling, a throbbing sensation, a shadow in the vision, or a reduction of vision within the operated eye. Patients, who develop these symptoms suddenly, should attend the eye casualty department as soon as possible for further assessment.

Dislocation/extrusion

The implant may move from its original position. The surface tissue over the implant (conjunctiva) might uncommonly break down leading to exposure and infection of the implant. A further operation may be needed to remove the implant in some cases, although it is uncommon.

Corneal damage

Corneal decompensation which is clouding of the normally clear front window of the eye may occur if the implant rubs against it. This is very uncommon.

Loss of vision

Some degree of blurred vision is expected for some weeks after surgery. The above mentioned list of possible complications may uncommonly lead to irreversible loss of vision after surgery or rarely loss of eye. The risk varies with the type and stage of glaucoma, the patient's age, race, other eye conditions and previous surgery.

Please seek urgent advice if there is a significant sudden change in your vision at any time after your surgery.

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Sympathetic ophthalmia

The other eye may very rarely be affected by surgery in one eye, by simultaneous inflammation in the two eyes, causing loss of vision.

Severe complications are uncommon and steps are taken to prevent them but it may not be possible in all cases.

What are the risks of not having the procedure (or glaucoma treatment)?

If the eye pressure remains elevated despite medical therapy then there is a risk that your vision will deteriorate. Vision loss from glaucoma is irreversible and permanent. The rate at which vision may deteriorate varies vastly between different patients.

Are there any alternatives?

There are many ways to treat glaucoma, such as eye drops, surgery, laser surgery, and other procedures. Your surgeon will recommend options for your glaucoma treatment after assessing number of specific characteristics including; the eye pressure, stage and type of disease, state of your eye tissues, other eye conditions, your general health and relative risks of different procedures.

Alternative standard surgical treatments for uncontrolled glaucoma include glaucoma filtration surgery (trabeculectomy) and glaucoma tube implantation, iStent implantation, Trabeculotomy (Trabectome) and Laser trabeculoplasty are other minimally invasive options suitable in some cases. These are recommended according to suitability for the individual case.

XEN Gel Stent may be able to provide an improvement to your eye pressure with less potential risks than the other major standard surgical options. Your doctor will be able to discuss this further. You are encouraged to make an informed choice on what procedure you would like to have/ not have and your decision will be respected fully.

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What happens before your operation?

Before the operation you will be asked to attend a pre-operative assessment appointment to check that you are fit for the procedure and anaesthetic.

Please bring an up to date list of your medications and a brief summary of your medical history with you to this appointment; if you are unsure of anything please check with your GP. During this visit your general health and suitability for anaesthetic will be assessed. Any investigations such as blood tests will also be undertaken as appropriate.

If you use blood thinning medications such as Aspirin, Warfarin and Clopidogrel or new blood thinning medications such as Rivaroxaban or Dabigatran then please do tell your eye surgeon during the consultation and the nurse at the preoperative assessment. Some of these medications **will need to be stopped temporarily** to decrease risk of bleeding with surgery. The safety and duration of this will be done in discussion with your doctor/haematology team, and you will be advised accordingly. It may not be possible in some cases to perform this procedure if the risk of bleeding is considered high.

You should continue to use any eye drops and tablets for your glaucoma as directed by your ophthalmologist until your operation. In some cases you may be asked to stop the drops for a certain period before the operation to reduce the risk of eye pressure going too low immediately after the operation.

What happens during the operation?

The operation is usually performed under a local anaesthetic, which means that you will be awake, but your eye will be numbed so you will not feel any pain during the operation. The eye will be anaesthetised first with eye drops and then an injection of anaesthetic will be administered around the eye. The anaesthetic injection itself may cause some discomfort; a slight sensation of pressure as the anaesthetic is delivered. The injection prevents pain and excessive eye movement during surgery. For many hours you may either see nothing out of the eye or have very blurred vision. Your anaesthetist will discuss this with you before the surgery.

During surgery your face will be covered by a sterile sheet, or drape, which keeps the operation site sterile and also prevents you from seeing any of

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the surgery. You will be aware of the surgeon working around the eye, but should not feel pain.

Somebody will usually be holding your hand during surgery and in the event of any pain or discomfort, you should squeeze their hand. This will alert the surgeon so that they can stop the surgery and top-up the anaesthetic if needed. You are also likely to hear the surgeon speaking to the scrub nurse and other members of the surgical team.

Sometimes general anaesthetic may be considered to put you to sleep during the operation if local anaesthetic is not considered suitable for you or if you specifically choose so.

The procedure itself only takes about twenty minutes in addition to the cataract surgery. In some cases it may take longer. It is often performed at the end of cataract surgery but can also be done separately.

During the operation, the XEN gel stent is placed through a small (approximately 1.9mm), self-sealing, corneal incision via a preloaded injector with a small needle. Using an ab-interno (from the inside) approach, the surgeon advances the inserter across the front part of the eye and inserts the implant. This small incision approach to glaucoma surgery is also known as micro-invasive glaucoma surgery (MIGS)

What special medications are used during the operation?

During the surgery, a drug called Mitomycin- C may be applied to the surface of the eye for a brief period of time to reduce the amount of scarring after surgery which could otherwise prevent the Glaucoma drainage from functioning. This is the same medication used in Augmented Trabeculectomy (standard glaucoma filtration surgery). It may be injected under the surface layers (conjunctiva and tenon's) of the eye. Rather than injecting the surgeon may make a limited opening in these layers to apply this medication and improve efficacy and/or safety of the procedure.

What happens after the operation?

After the operation, your eye will be covered by a protective plastic shield and an eye pad which stays in place overnight. An appointment will be arranged to review you on the following day.

Usually you will be able to go home after a few hours. In some circumstances you may need to stay in overnight such as if you have had a general anaesthetic.

Your eye may begin to feel sore once the anaesthetic starts to wear off. The pain isn't usually too bad and you can take your usual pain relief, such as paracetamol or ibuprofen, to help. You should be able to take off the dressing the following morning at home and start drops after cleaning the eye. Your eye is likely to look red and have some bruising around it.

Patients are advised to ask a friend or relative to accompany them home after surgery.

What should I expect to feel during the postoperative period?

It is normal for the vision to be blurred and the eye to be uncomfortable and red after surgery. The period of blurring is variable. The vision may be particularly blurred for a few days following surgery, and then start to improve.

Your eye may be watery and sore for some time after surgery, usually for a few a days. It can take two to four weeks for the eye to feel normal and the vision to stabilise after surgery.

Will I have to use eye drops after surgery?

Special postoperative drops are given to every patient and are to be used regularly

- An antibiotic (e.g. **Chloramphenicol**)
- An anti-inflammatory steroid (e.g. **Maxidex or Dexamethasone**). This will initially be required frequently for few weeks and then reduced over further few weeks.

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- A drop to keep the pupil dilated (**mydrilate or atropine**).

The postoperative eye drops will normally need to be taken for up to approximately three months. Each time you attend the outpatient clinic any changes to your eye drops will be discussed with you. If you are running out of the drops you will need to get a repeat prescription for them **from your GP** before you run out.

The drops should not be stopped or the dosage changed without consulting your eye surgeon.

It is important that any eye drops for the other eye are continued as before unless advised otherwise.

What happens to the eye pressure immediately after surgery?

The pressure is expected to drop in the majority of the cases but you will not notice any special effect. Each patient is different and the exact eye pressure result will vary between patients. In some cases the XEN Gel Stent is being used to complement the pressure lowering effect of your eye drops and you may need to continue using these. The change in glaucoma drops, if any, will depend on the pre-treatment pressure, the number of eye drops used before surgery and the response of your eye to the surgery. Some patients may be able to stop or reduce the glaucoma drops they use.

How often will I need to be seen after surgery?

After the first review on the day after surgery, all patients are seen a week later and regularly for some weeks following the operation. In individual cases it may be necessary to see you more often. The exact timing depends on how the eye settles down.

It is very important that you attend all your clinic appointments and use your eye drops as prescribed.

Are additional procedures required after the operation?

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You may require injections of steroids or 5-Fluorouracil (a drug that reduces scarring) to prevent scar tissue forming which can block the drainage channel. These are usually done as an outpatient procedure under adequate anaesthesia.

If excessive healing leads to scarring then it may need to be cut to increase the drainage with a procedure called 'needling'. This is required in about a third of cases.

Uncommonly, you may need to go to theatre if the implant is not in correct place or if additional stitches put to secure any wound that would have been made at the surgery.

Very uncommonly if the implant extrudes you may need revision of the drainage with either repositioning, removal or replacement of the implant.

If the procedure does not work or if it stops working later then you may be offered further surgery for controlling your eye pressure.

What can I usually do after the operation?

- Most normal non-strenuous daily activities
- Walking (Be careful on the stairs)
- Watching television
- Reading
- Move around the house and bend carefully
- Wear sunglasses outside in windy weather and/or bright sunlight
- Sexual relations should be limited to a kiss and a cuddle until the eye is healed

What should I avoid after the operation?

For at least four weeks after the operation please avoid:

- Rubbing your eye;
- Any vigorous activity including contact sports, squash, badminton, swimming, gardening and vacuum cleaning;

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- Driving for a **minimum of four weeks** after the operation or until the eye has settled, whichever is later. Before starting to drive please confirm with the surgeon that your eye pressure has stabilised. You should be able to read the new style car number plate at 20 metres and your eye should be comfortable;
- Eye make-up;
- Splashing water into the eye. (Please shower from the neck down. Back-wash your hair for the first week. This is to avoid getting soap or shampoo in the eye;
- Dusty atmospheres.

When can I go back to work?

The duration of time off work will depend on a number of factors such as the nature of your work, the state of the vision in the other eye and the pressure in the operated eye. Typically someone working in an office environment would require two weeks off, if the postoperative course is smooth. Someone whose occupation involves heavy manual work or work in a dusty environment may require four weeks or more (such as construction workers, farmers). This will depend on number of factors and patients are advised individually.

Can I travel abroad after the operation?

Going on an aircraft after a few weeks is safe. It would be preferable not to travel abroad until things have stabilised, in case an emergency should arise. This period depends on how your eye recovers after the operation and advice is given individually. Please ensure you are available for regular follow-up for at least six weeks after the surgery.

Can I wear contact lens wear after surgery?

It may be possible to restart contact lens wear around four weeks after surgery. Not everyone can continue to wear contact lenses after XEN gel implant surgery, so this is something to consider before having the operation.

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When do I need to contact the hospital?

Contact the hospital or eye casualty urgently if:

- Your eye becomes more painful or red other than on the day you went home;
- Your eye develops a sticky discharge;
- Your lids start to swell;
- Your vision begins to deteriorate.

Useful contact details in case of urgent clinical need

Eye Casualty at **University Hospital Coventry and Warwickshire**

Telephone: 024 7696 6627

Open from: Monday to Thursday 8.30am – 4.30pm

Friday 8.30am – 4.00pm

Saturday 8.30am – 12.00pm

Outside these opening times please attend the Main Accident and Emergency Department at University Hospital Coventry and Warwickshire.

Useful contact details for further information

Secretaries:

Michelle Donnelly: 024 7696 6501

Jayne Owen: 024 7696 6502

Useful Contact details for further information

International Glaucoma Association

Woodcote House, 15 Highpoint Business Village, Ashford, Kent TN24 8DH

Telephone: 1233 64 81 70 Email: info@iga.org.uk

Website: www.glaucoma-association.com

Patient Information

Royal College of Ophthalmologists

17 Cornwall Terrace, London NW1 4QW

Telephone: 020 7935 0702

Website: www.rcophth.ac.uk

Royal National Institute of Blind People

105 Judd Street, London WC1H 9NE

Telephone: 0303 123 9999 Email: helpline@rnib.org.uk

Website: www.rnib.org.uk

Important disclaimer

The information provided in this information booklet is designed as an addition to, and not a substitute for, professional healthcare advice by a qualified eye surgeon, doctor or other healthcare professional, which will be tailored to a patient's individual circumstances. While every step has been taken to compile accurate information and to keep it up to date, its correctness and completeness cannot be guaranteed.

Patients are encouraged to seek further information and or opinion, as they feel necessary, in making decision about their surgery and not rely solely on the information in this booklet

The Trust has access to interpreting and translation services. If you need this information in another language or format please 024 7696 6501 contact and we will do our best to meet your needs.

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