

Patient Information Leaflet

LuxSmart™ Preloaded Aspheric Intraocular Lens
LuxGood™ Preloaded Aspheric Intraocular Lens

Models:

LuxSmart™ (LUXSMART Preloaded Hydrophobic Yellow Lens)
LuxSmart™ Crystal (LUXSMART Preloaded Hydrophobic Lens)
LuxGood™ (LUXGOOD Preloaded Hydrophobic Yellow Lens)
LuxGood™ Crystal (LUXGOOD Preloaded Hydrophobic Lens)

This leaflet will help you understand general information on cataracts, treatment with surgery and intraocular lenses, and is not a substitute for advice from your ophthalmologist. Please discuss any questions with your ophthalmologist.

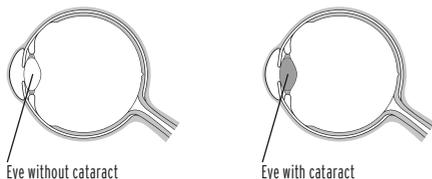
Intended Purpose

LuxSmart™ and LuxGood™ are intraocular lenses, designed to replace the natural crystalline lens of the eye in adults following cataract surgery.

What are Cataracts?

Cataracts are a clouding of the eye's natural lens and usually develop as a normal part of ageing.

Cataracts develop when protein builds up in the lens of your eye and makes it cloudy. This keeps light from passing through clearly and can interfere with your vision.

**Treatment for Cataracts**

Surgery is needed to remove the cloudy lens and replace it with a permanently implanted artificial lens, called an intraocular lens (IOL). This transparent plastic disc has a similar shape to the natural lens and supports for stability. Many different types of IOL are available to suit different cases.

Once the cataract is removed, LuxSmart™ or LuxGood™ IOLs are placed in the same lens capsular bag that the cataract previously occupied. These IOLs correct vision and help your eye focus at a predetermined distance after surgery. These IOLs come in different powers to correct different refractive errors such as myopia and hyperopia.

LuxSmart™ Crystal and LuxGood™ Crystal feature an acrylic hydrophobic cross-linked copolymer material which includes a UV absorber to protect against light that could lead to ocular damage.

LuxSmart™ and LuxGood™ feature an additional blue light filtering chromophore to protect against blue light. The LuxSmart™ and LuxGood™ IOLs utilize a design that is based only on refractive profiles. LuxGood™ IOLs have no aberration optics and LuxSmart™ IOLs have negative spherical aberration optics. Your ophthalmologist will determine the best lens for you based on your needs and the results of the examination.

Potential Risks

Cataract surgery is safe but does have risks of complications. Complications may occur as a result of the removal of your cataract whether an intraocular lens (IOL) is implanted. Complications of cataract surgery range from minor, usually temporary side effects, to sight-threatening complications. Significant sight-threatening complications are extremely rare and include, but are not limited to: inflammation, infection, bleeding, swelling, and retinal detachment. People with existing medical conditions affecting the eye might be at a higher risk of developing complications, your ophthalmologist will weigh the potential benefit/risk ratio.

Sometimes after cataract surgery, you may find that things start to look cloudy again. It happens because the lens capsule -- the part of your eye that holds your new artificial lens in place -- begins to thicken up. You may hear your doctor call this by its medical name: posterior capsule opacification. The problem may not show up right away. You may notice it months or years later.

Your doctor may suggest a procedure called YAG to fix it. This surgery takes a few minutes and is painless. A surgeon uses a laser to open up the thickening around the lens capsule and let more light get through your artificial lens. That will clear up your cloudy vision.

Routine eye exams remain very important after cataract surgery to monitor the health of your eyes and the clarity of your vision. Your ophthalmologist will advise on the frequency of these examinations.

Prior to the surgery, your doctor will do some tests to measure the size and shape of your eye to determine the size and strength of the intraocular lens. Your ophthalmologist will discuss the different IOL choices with you.

Your doctor will also explain the cataract procedure and a pre-admission assessment will be performed. Your ophthalmologist will also need to know your medical history to plan the best treatment. Tell your ophthalmologist about any health problems you have. Some may interfere with surgery, anesthesia, recovery and ongoing medical treatment following recovery.

Cataract operations are usually performed in a day surgery facility, so you should be able to return home on the same day as the procedure, without any overnight stay. You may have a protective pad placed on your eye which you will need to wear up until your follow up appointment. You will also be shown how to correctly put in the eye drops.

After Cataract Surgery:

- Be sure to attend all follow-up visits so that your eye doctor can monitor healing.
 - Expect your vision to begin improving within a few days. Your vision may be blurry at first as your eye heals and adjusts.
 - It is normal to feel itching and mild discomfort for a couple of days after surgery. Avoid rubbing or pushing on your eye.
 - Avoid most exercise or heavy lifting. Your doctor will tell you when you can do those activities again.
 - Your doctor may ask you to wear a protective shield for a few days after surgery. This is especially important during sleep.
 - Your doctor may prescribe eye drops or other medication to prevent infection, reduce inflammation, and control eye pressure.
 - After a couple of days, most of the discomfort should disappear. Often complete healing occurs within eight (8) to twelve (12) weeks.
 - Contact your doctor immediately if you experience any of the following:
 - Vision loss
 - Persistent or severe pain
 - Increased eye redness
 - Light flashes or multiple new spots (floaters) in front of your eye
- IOLs are made from plastic polymers, so they are expected to have a long lifetime.

Reporting a serious event

Always follow your doctor's instructions. Any serious event that you experience in relation to the device, you can report to the manufacturer or the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

Sponsor Information

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