

Patient Information Brochure

ClearView™ 3 Multifocal Intraocular Lens

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CAUTION: Federal (USA) law restricts this device to sale by
or on the order of a licensed practitioner



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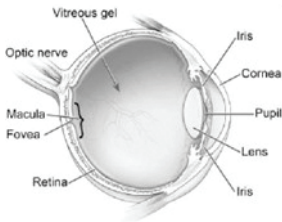
Introduction

Every year about 4 million Americans have cataract surgery. It is a common procedure which is performed by eye surgeons daily. This brochure will help you understand your cataract, your available options to correct it and the risks and benefits of choosing the ClearView 3 multifocal intraocular lens.

What is a cataract?

Inside your eye there is a natural lens that helps focus light onto on to a structure called the retina. At birth the natural lens is clear. Over time, the natural lens becomes "cloudy" and that makes vision less clear. This natural process happens slowly over years in most cases. It can get to a point where everything is too blurry to see clearly. The only way to treat this is to have an eye surgeon remove the cataract and replace it with an intraocular lens (IOL).

Figure 1: The eye



What is an intraocular lens?

An intraocular lens, or IOL, is a plastic replacement lens for your cataract. It works the same as your natural lens. Once your eye surgeon replaces the cataract with the IOL, vision is usually restored within days.

Figure 2: The Lenstec Softec HD Intraocular Lens



What is cataract surgery?

Cataract surgery is performed by an eye surgeon to replace the cataract with an IOL. Before surgery, the eye doctor or clinic staff will measure your eye to see what "prescription" of IOL you will need (which is referred to as biometry), just like would be required if you were getting eyeglasses.

On the day of surgery, you will be asked to arrive at the surgical facility early enough to have numbing drops placed on to the eye so that you don't feel discomfort during surgery. Once the eye is numb the doctor will view your eye under a microscope and then make a small incision on the outside layer of the eye. He or she will then remove a small part of the front of the lens capsule, which is like a clear bag that holds the cataract. In the next step, the surgeon will remove the cataract by vacuuming the cloudy lens proteins carefully using a very small ultrasound instrument. The surgeon will then insert the rolled, or folded, IOL through the same small incision that was made before. It unrolls inside the eye. Once the IOL is in place the surgeon will seal the incision site and the surgery is done. The surgeon may cover your eye with a shield to protect it. You will need to have someone available to drive you home after surgery.

The surgeon will likely prescribe some eye drops that you will be asked to place in your eye over several days. This is to help with the healing process and to prevent infection. Some patients are able to see well between 1-2 days after surgery. Others take a little longer because healing is different for everyone. By 4-6 weeks after surgery you can expect to be well healed.

Just to make sure healing is going as expected, the eye doctor will schedule several visits after surgery for you to come back to the clinic to have your eye examined. Call your eye doctor if you have any concerns after surgery.

What are the potential risks associated with cataract surgery?

As with any surgery there are risks of side effects or complications. Some of the most common are a reaction to medicines used during surgery, infection, increased eye pressure and pain. There is also a small chance that your vision can get worse after surgery. Your eye doctor can help you understand these risks better. This is not an all-inclusive list. Details for all potential risks should be discussed with your physician.

What types of IOLs are available for my surgery?

There are many different types of IOLs available for your surgery and these choices should be discussed with your eye doctor carefully.

Monofocal IOLs

A monofocal IOL is the most commonly used IOL for cataract surgery. With monofocal IOLs a single distance is in focus without vision correction options (like eyeglasses or contact lenses). Objects outside this distance are blurry unless bifocal glasses or contact lenses are worn.

Accommodating IOL

An accommodating IOL can also be used for cataract surgery. Accommodating IOLs are inserted in the same way as monofocal IOLs. These IOLs have one prescription power that changes locations as it “flexes” inside your eye to help you see distance, intermediate and near. That can mean you need vision correction options (like eyeglasses or contact lenses) less than you would with a monofocal IOL.

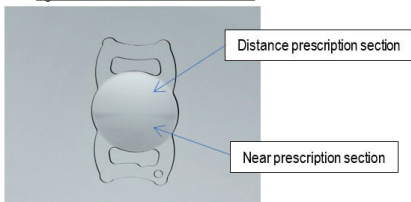
Multifocal IOLs

Multifocal IOLs provide focus for distance and near (and some for intermediate as well) so you should not have to wear vision correction options for many tasks in your life. These lenses have different prescriptions built into the lens so there is no need for the IOL to flex inside the eye. The prescription zones help you see things nearby and far away. Traditional multifocal IOLs are made with circular rings that have different zones to help you see well at all distances.

ClearView 3 Multifocal IOL

The ClearView 3 is a multifocal IOL that is used to replace the cataract in your eye. The ClearView 3 lens includes two distinct zones for focusing light, one for distance vision and one for near vision. It is designed differently than most multifocal IOLs. The ClearView 3 does not have circular rings but rather has two separate prescription sections that give both images in the eye at the same time (one blurred and one clearer).

Figure 3: LensteC ClearView 3 Multifocal IOL



When compared to patients receiving a monofocal IOL, the clinical study for approval demonstrated that the ClearView 3 patients had about equal visual acuity for far and intermediate distances, and had better visual acuity for near (unless the monofocal patients wore reading glasses). Patients who received the ClearView 3 did have a higher rate of vision distortions, however, vision distortion occurs with all multifocal IOLs.

Purpose of the device (indications for use)

The ClearView 3 multifocal intraocular lens is indicated for primary implantation for the visual correction of aphakia, in adult patients with 1 diopter or less of pre-existing corneal astigmatism, in whom a cataractous lens has been removed. The lens mitigates the effects of presbyopia by providing a bifocal correction. Compared to an aspheric monofocal IOL, the lens provides improved near visual acuity, while maintaining comparable distance and intermediate visual acuity. The lens promotes the less frequent use of vision correction choices at near distance (including glasses, contact lenses, magnifying glasses, and digital adjustments on electronic devices), compared to an aspheric monofocal IOL, as reported in patient-reported outcomes. The ClearView 3 multifocal IOL is intended for capsular bag placement only.

When the device should not be used (contraindications)

Outside of general contraindications for ocular surgery, the following specific contraindications apply:

Uncontrolled glaucoma, microphthalmia, chronic severe uveitis, retinal detachment, corneal decompensation, diabetic retinopathy, iris atrophy, perioperative complications, potentially foreseeable postoperative complications and other conditions which an ophthalmic surgeon might identify based on their experience.

Risks vs benefits

There are some risks that are associated with cataract surgery itself and some that are associated with the ClearView 3 IOL.

All surgery has potential risks. Cataract surgery is no different. Vision can be worse after cataract surgery if there are complications during surgery or if infection sets in after surgery. This is rare but it is possible.

The ClearView 3 also has risks associated with it. More patients that had the ClearView 3 IOL reported that they saw severe symptoms of "halos," "glare," "streaks of light," or "double images" compared to the monofocal IOL. These types of events are commonly referred to as "visual distortions" or "visual disturbances." These made seeing things more difficult for them. This issue is greatly reduced if you select a monofocal IOL in place of a multifocal IOL. The ClearView 3 group also had a larger percentage of patients which needed to have secondary surgical intervention, or additional surgery, to correct or adjust something because of the ClearView 3 itself. This is something that should be discussed with your eye surgeon in more detail.

The benefit of cataract surgery with a monofocal IOL in general is that, by removing the cataract, distance vision is clear. If the ClearView 3 is used instead of a monofocal IOL most patients are less reliant on glasses.

Warnings

- You may need to use vision correction options (like eyeglasses or contact lenses) for some tasks after surgery.
- You should exercise caution when driving at night or in poor visibility conditions. Part of the main clinical study used to approve the ClearView 3 was a simulated driving test. Patients in the control group were able to recognize signs and road hazards sooner than in the multifocal group. This is consistent with previously approved multifocal IOLs.
- Patients receiving the ClearView 3 had poorer contrast sensitivity than those receiving a monofocal IOL. This means that they may have greater problems seeing things that do not have high contrast and this is often more of a problem in dim lighting. The ability to clearly see might be worse with the ClearView 3 than if you get a monofocal IOL. This can cause difficulties with driving, especially under conditions of poor lighting. If you get the ClearView 3 multifocal you should be cautious while driving, especially in dim lighting.
- There are some cases in which the ClearView 3 IOL should not be implanted and your eye surgeon is aware of those. This could include other uncontrolled eye diseases you may have or problems that could occur during surgery. It is important to speak with him or her before having surgery about any eye issues you have had. For example: dry eye disease, glaucoma, macular degeneration and diabetic retinopathy may be reasons to avoid the ClearView 3 IOL.
- After surgery, it is possible that you will see halos, or glare or 'ghost' images around things, or that some things look blurry in general. Squinting or partially closing the eyes may reduce or block distance vision, therefore it may be helpful to open the eyes wider if distance vision is blurry. However, other vision problems will not be helped by this and will not be helped by anything the patient can do. Patients with larger pupils could be more impacted by these problems. Your doctor will measure your pupils prior to surgery and let you know if this is a concern.
- In the clinical trial used to approve the ClearView 3 the group of people that got the ClearView 3 had a higher rate of severe visual disturbances (glare, halos, double images, and streaks of light) than the group that got the approved monofocal IOL. These visual symptoms may contribute to difficulties with driving under certain conditions. Patients should exercise caution.
- You should wear UV blocking sunglasses after surgery because it is not known how well IOLs protect your eyes from UV light.
- Patients with the largest pupils (7.5 mm or larger) have more chance of more light going around the IOL. This is a generic problem with all IOLs. It could make visual disturbances worse for you.
- People with very small pupils (smaller than 2.75 mm) also could have a problem with their vision.
- The bottom of the ClearView 3 optic has a very small part which has less prescription than the rest of the IOL. See the figure below. The green part is the distance prescription. The red part is the near prescription. Just below the red is a white portion which is the area being discussed here. In eyes that have very large pupils it is possible that you may see poorly because of that white portion. No patient in the clinical trial used to approve the ClearView 3 complained of this problem but it is something that could happen in theory.

Figure 4: ClearView 3 optic portion



- You should contact your eye doctor if you have a significant decrease in vision or a significant increase in pain, redness, itching, discharge or sensitivity to light, as any of these could point to one of several complications that need to be treated immediately.
- The ClearView 3 was only studied with both eyes implanted (not just a single eye). Your results with just one ClearView 3 might vary.
- It is possible that the capsule that holds the IOL will become cloudy over time. This is often referred to as a capsular scar. This is easily treated with a minor laser procedure that occurs more often in patients who received multifocal IOLs than those that get a monofocal IOL. The capsular scar in patients that get an ClearView 3 may be more bothersome sooner than those that get a monofocal IOL.
- Patients with the following conditions: uncontrolled glaucoma, microphthalmia, chronic severe uveitis, retinal detachment, corneal decompensation, diabetic retinopathy, perioperative complications, previous ocular surgery, non-age related cataract, vitreous loss, iris atrophy, severe aniseikonia, ocular hemorrhage, macular degeneration or suspected microbial infection could be at risk for complication(s) following implantation of the ClearView 3. If you are unsure of your eye conditions speak with your eye doctor before surgery.
- The ClearView 3 lens has only been studied in adult patients. Children are likely to have special issues with the ClearView 3 lenses related to larger pupil size and difficulty in describing problems with visual disturbances. Implantation in children is not recommended.
- In the clinical study for approval some patients who received the ClearView 3 IOL had substantial changes in the strength of glasses needed to see clearly for things far away. These changes happened between doctor visits at least 1 month after surgery. These changes can cause changes in the sharpness of their vision.
- A higher amount of ClearView 3 patients had an increase in near sightedness (the inability to see distant objects clearly) which may increase the chance of IOL replacement surgery.

Precautions

- Only patients who were considered in good general and ocular health (NOT diagnosed with: severe retinal or corneal disorders, swelling of the intraocular anatomy, ocular muscle disorders, abnormal ocular anatomy and not taking medications that could make ocular surgery more troublesome) and who were 22 years of age or older participated in the study. Therefore, the safety and effectiveness of use of the ClearView 3 device in these patients is not known.
- Some eye disorders, like glaucoma, diabetic retinopathy or macular degeneration may not allow you to get perfectly clear vision even after implanting of an IOL. Also, if you have very droopy eyelids (called ptosis), you may have trouble seeing either near or far with this IOL. This is something your eye doctor will check for before your surgery.
- It is important that you follow the medication regimen that your eye doctor prescribes, before and after surgery. If you do not, your eyes could become inflamed or infected and your vision may get worse.

Postoperative care instructions

After surgery, you will need someone to drive you home. The eye doctor will need to see you after surgery, usually the next day, to check your eye and the results of surgery. He or she will likely give you some eye drops to help reduce inflammation and possible infection, which should help the healing process. You will be asked to come back to the doctor's office a few times after surgery so the doctor can check your eye again. If you have any issues with your vision discuss them with your eye doctor.

Making the best choice for you

During the clinical trial, the ClearView 3 was compared to a standard monofocal IOL at 18 different clinical sites across the US for 1 year after surgery. The study compared distance vision, intermediate vision and near vision between the two groups. It also had the eye doctors involved make note of any and all adverse outcomes that happened in either group. These are things that could happen following any routine cataract surgery. It also had the patients complete a survey asking them how often they used vision correction options (like eyeglasses or contact lenses) for distance, intermediate and near. The same survey asked the patients about the presence of and the level of difficulty or disruption from the visual disturbances they saw. Finally, the survey asked them how satisfied they were with their distance, intermediate and near vision without the vision correction options (like eyeglasses or contact lenses). The tables below will summarize the results of that study.

Table 1: Results from clinical study in the US

Test performed	Results	Summary
Distance vision measured on a chart in the clinic	The distance vision was comparable between the two groups	Both groups of patients had similar visual acuity
Intermediate vision measured on a chart in the clinic	The intermediate vision was comparable between the two groups	Both groups of patients had similar visual acuity
Near vision measured on a chart in the clinic	The near vision without glasses was better in the ClearView 3 group	ClearView 3 patients saw better for near vision than the patients that had the monofocal IOL, when looking at the eye chart
Contrast sensitivity (ability to distinguish different shades of grey or shades of a color) measured on a chart in the clinic	Contrast sensitivity was somewhat poorer in the ClearView 3 group than it was in the control group	The control group had better contrast sensitivity results than the ClearView 3
Survey results: Distance vision without vision correction	The distance vision without vision correction was comparable between the two groups	Both groups of patients used their vision correction similarly at far distance
Survey results: Intermediate vision without vision correction	The intermediate vision without vision correction was better in the ClearView 3 group	Both groups of patients used their vision correction equivalently at intermediate distances
Survey results: Near vision without vision correction	The near vision without vision correction was better in the ClearView 3 group	ClearView 3 patients reported use of vision correction less for near distances
Survey results: Visual distortions (halos, glare, starbursts, double vision)	The number and amounts of distortion reported was worse in the ClearView 3 group	The number of and level of difficulty or disruption due to distortions reported was worse in the ClearView 3 group
Survey results: Overall satisfaction with near, intermediate and distance vision	Satisfaction was better in the ClearView 3 group for intermediate and near vision, whereas the satisfaction in the monofocal lens group was better for distance	Patients were more satisfied with their distance vision with the monofocal lens, whereas patients with the ClearView 3 were more satisfied with their intermediate and near vision.

In the same study the clinical site staff measured adverse outcomes that occurred in patients. Overall, both groups had similar percentages of these adverse outcomes. The table below will list those specific instances of adverse outcomes that occurred. You will see there was a greater number in the ClearView 3 group than there was in the monofocal IOL group. It is worth noting that each of the negative outcomes are known outcomes from cataract surgery in general and not new to this clinical study.

Table 2: Adverse event from clinical study in the US

Type of negative outcome	Results for the ClearView 3	Results for the monofocal IOL	Summary
Key adverse events occurring at any time during the study			
Swelling of the retina (cystoid macular edema)	2.0 %	2.7%,	This was similar for both groups of patients
Blockage of fluid traveling within the eye caused by the iris (colored part of the eye) (pupillary block)	0.2%	0%	This was similar for both groups of patients
Detachment of retina from the back of the eye (retinal detachment)	0.2%	0%	This was similar for both groups of patients
Additional surgery (total secondary surgical intervention)	1.8%	0.9%	ClearView 3 patients experienced more instances of secondary surgical intervention for reasons not related to the IOL optic than the monofocal group
Additional surgery related to the ClearView 3 (visual disturbance or decrease in vision) (secondary surgical intervention reasons related to the IOL optical characteristics)	0.9%	0%	ClearView 3 patients experienced more instances of secondary surgical intervention for reasons related to the IOL optic than the monofocal group
Key adverse events existing at the 1 year follow up visit			
Swelling of the cornea (corneal stromal edema)	0.2%	0%	This was similar for both groups of patients
Swelling of the retina (cystoid macular edema)	0.2%	0%	This was similar for both groups of patients

As discussed above, the ClearView 3 group had patients report more visual disturbances than those of the monofocal group. Visual disturbances are the main negative outcomes for most patients who receive multifocal IOLs experience.