

**PATIENT  
INFORMATION  
BROCHURE**

Alcon AcrySof<sup>®</sup> IQ ReSTOR<sup>®</sup> +2.5 D  
Multifocal Intraocular Lens (IOL)

Model SV25T0

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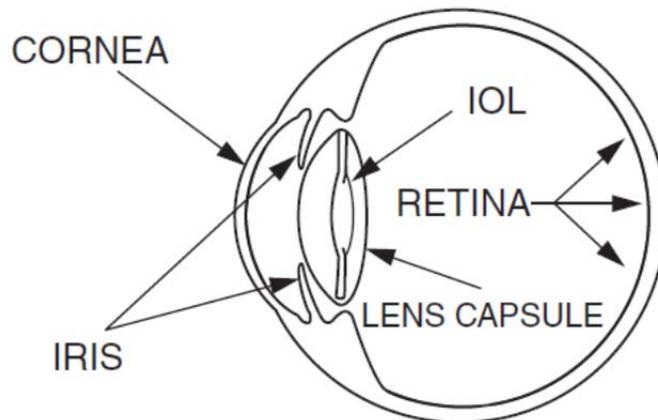
**Model SV25T0**

This brochure has been written to assist you and your surgeon in making an informed decision regarding the best intraocular lens (IOL) for your cataract surgery. Your surgeon will advise you about the potential risks and benefits of the surgical procedure for cataract removal and IOL implantation. This brochure will aid you in deciding if an Alcon AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 would be an appropriate choice for you. Please see the “What types of IOLs are available for this procedure” section for other options you may have.

The AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 has the same basic shape and identical materials as Alcon monofocal IOLs and, like a monofocal lens, will provide you with good far vision. Like a monofocal lens, the purpose of the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 is to focus images clearly onto the back of your eye (retina) to allow clear vision after the cataract removal. In addition, the center of the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 allows for better near (reading) vision and intermediate (computer work) vision versus what a monofocal lens would provide.

**What is an Intraocular Lens (IOL)?**

An intraocular lens, commonly referred to as an IOL, is an artificial lens that is implanted into the eye to replace the natural lens when a cataract is removed. Figure 1, below, shows the basic parts of the human eye with an implanted IOL.



**Figure 1 – Drawing of the Human Eye with an Implanted IOL**

**What is a cataract?**

Your eye functions much like a camera. Your natural lens focuses images onto the back of your eye so you can see clearly, much like the lens of a camera focusing images onto film for a clear picture. At birth, your natural lens is clear. However, as you age, the lens may begin to gradually become "cloudy." This condition is called a cataract, and is usually a result of the natural aging process. As the lens becomes cloudier, your quality of vision may decrease.

Surgery is the only way a cataract can be removed. You should consider surgery when cataracts cause enough loss of vision to interfere with your daily activities.

### **What is the surgical procedure to restore my vision?**

After you and your eye doctor have decided that you will have your cataract removed, your eye will be measured. This will help to determine the suitable IOL for you that will be placed in your eye during surgery.

When you arrive for surgery, you will be given eye drops and perhaps medicines to help you relax. Cataract surgery techniques vary widely. However, the eye is always numbed to make the operation painless. To perform surgery, your eye doctor will use a microscope to have a magnified view of your eye. Your natural lens sits in a bag-like structure called the lens capsule. The lens capsule is located just behind the colored part of your eye (iris). A small incision is made in the outer surface of the eye. Through this opening, the eye doctor removes the center part of the front of the lens capsule and then inserts a tiny instrument to break-up and remove the cataract. An IOL is then placed into the capsule to replace your natural lens that your eye doctor has just removed. The IOL will focus light inside the eye to allow you to see. The surgeon will usually place a shield over your eye after surgery. You will be ready to go home after a short stay in the outpatient recovery area. Plan to have someone else drive you home.

### **Potential Risks Associated with Cataract Surgery**

As with any surgery, there are risks and potential complications associated with routine cataract surgery and IOL implantation. General surgery risks include reactions to medicines, bleeding, infection, inflammation, redness, scratchiness of the eye, sensitivity to light, and increased eye pressure. There is a small chance that your vision could be made worse by the operation. Please discuss these general risks associated with cataract surgery with your eye doctor.

### **What types of IOLs are available for this procedure?**

There are many different IOLs to choose from. Your eye doctor will discuss your options, including the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 and other multifocal IOLs. For example, other Alcon multifocal IOLs have different optical strengths for near vision. Other IOL types are also available such as monofocal IOLs, accommodating IOLs (which change focus to allow patients to see clearly at distance, intermediate or near) and toric IOLs (which provide clear distance vision for patients with pre-existing astigmatism, an irregular corneal shape, by compensating for the irregular cornea). Discuss all of your IOL options with your eye doctor.

In general, IOLs have two basic features. The optic portion is the round part of the IOL which focuses an image onto the back of your eye. Two arm-like structures called haptics are attached to the edge of the optic. The haptics help to maintain the location of the IOL in the eye.

A monofocal IOL is designed to provide clear distance vision. This means you will usually be able to see objects far away, but there is still a chance that you may need glasses for distance vision. You will most likely need glasses for near vision activities such as reading, writing, and sewing, as well as intermediate vision activities such as applying makeup or shaving, and working on a computer. Let's look at the ideas behind the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0.

### **Alcon AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0**

The design of the Alcon AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 allows for clear distance vision (watching children playing in the backyard). The center of the IOL also allows for better near (reading) and intermediate (computer work) vision versus what a monofocal lens would provide. There is a chance that you still may need glasses for distance, intermediate, and near vision.

You will get the full benefit of the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 when it is implanted in both eyes. Please discuss with your eye doctor whether this is the right IOL for you.

### **Potential Side Effects Associated with the IOL**

Due to the design of multifocal IOLs, there are some side effects that can be associated with the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 which may be worse than with a monofocal

IOL, including visual disturbances such as glare, rings around lights, starbursts, and reduced contrast sensitivity (decrease in ability to distinguish objects from their background, especially in dim lighting). These side effects may make it more difficult to see while driving at night or completing tasks in low lighting conditions such as at night or in fog, or in a dimly lit room after surgery as compared to before surgery.

A night driving simulation study was previously conducted on patients implanted with other multifocal and monofocal IOLs where patients were asked to assess the effects of various lighting conditions on vision performance. The ability of multifocal IOL patients to detect and identify road signs and hazards at night was similar to the monofocal patients under normal visibility conditions. Sign identification in fog and glare conditions were more challenging for the multifocal patients compared to monofocal patients. The ability to detect hazards was also lower for multifocal patients than monofocal patients, especially when glare was present.

In Table 1 below, the number of patients who reported any visual disturbances, regardless of severity, during a clinical study conducted in the United States for the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL (Model SV25T0) and the monofocal IOL (Model SN60WF) are shown .

**Table 1: Rates of Visual Disturbances, 6 Months After Surgery**

	<b>Model SV25T0 (Multifocal)</b>	<b>Model SN60WF (Monofocal)</b>
<b>Visual Disturbance</b>	<b>Number reporting visual disturbance/ Number questioned</b>	<b>Number reporting visual disturbance/ Number questioned</b>
Glare	93/153 (61%)	85/160 (53%)
Halos	101/153 (66%)	62/160 (39%)
Starbursts	72/153 (47%)	62/160 (39%)
Hazy Vision	56/153 (37%)	54/160 (34%)
Blurred Vision	41/153 (27%)	45/160 (28%)
Distortion where straight lines look tilted	13/153 (8%)	8/160 (5%)
Distortion where flat surfaces look curved	7/153 (5%)	6/160 (4%)
Double Vision	11/153 (7%)	6/160 (4%)
Color distortion (objects appearing in different color than you know that they are)	10/153 (7%)	10/160 (6%)
Feeling sick to your stomach due to visual distortions	9/153 (6%)	13/160 (8%)

### Warnings

- As with other multifocal IOLs, there is a possibility that you may experience severe visual disturbances such as halos and glare. This may cause you to be dissatisfied to the point of requesting an explant of the IOL.
- There is a small risk of requiring further surgical treatment with any IOL implantation.
- You may have some visual disturbances such as halos (rings around lights) or glare.
- You may not get the best results with a multifocal IOL if before surgery it is determined that the front surface of your eye is irregular in shape (irregular astigmatism). Also, you may not get the best results if you have a higher amount (such as more than 1 diopter) of regular corneal astigmatism.
- It may be more difficult to see while driving at night or completing tasks in low lighting conditions such as at night or in fog, after surgery as compared to before surgery. Therefore, you should take extra care when driving at night.
- Contact your eye doctor immediately if you have any of the following symptoms after surgery: a significant decrease in vision, a significant increase in pain, significant itching, significant redness, watering of your eye, double vision persisting more than a few days, significant eye discharge, and

increased sensitivity to light. These symptoms could indicate potential serious postoperative complications including, but not limited to, eye infection, increased intraocular pressure, retinal detachment, wound leak, allergic reaction to medications, or lens dislocation.

- As with any surgery, there are risks and potential complications associated with routine cataract surgery whether or not an intraocular lens is implanted. Complications of cataract surgery range from minor, usually temporary side effects, to sight-threatening complications. Patients with pre-existing diseases or conditions (ie, chronic eye or lid infections, diabetes, intraocular inflammation) may be at higher risk of experiencing complications.
  - Sight-threatening complications include, but are not limited to, infection, bleeding inside your eye, corneal damage, chronic corneal edema (swelling of the cornea), macular edema (swelling of the central retina), severe inflammation, severe and/or chronic increased eye pressure, and retinal detachment. However, the frequency of significant sight-threatening complications is very low.
  - Minor temporary cataract surgery complications include, but are not limited to, reactions to medicines such as irritation or minor allergic response, mild inflammation, corneal edema (swelling of the cornea), and mild increased eye pressure.
- Cataract surgery with implantation of any IOL for patients with certain pre-existing conditions, such as low endothelial cell count (a measure of corneal health) or uveitis (intraocular inflammation), may experience worsening of such conditions, potentially leading to a poor postoperative visual outcome.
- Patients with pre-existing retinal problems that reduce their vision, such as macular degeneration or diabetic edema, may not benefit from or may have a poorer visual outcome following cataract surgery with multifocal IOL implantation.
- If you are implanted with a multifocal IOL, your doctor may find it more difficult to manage the following conditions:
  - age-related macular degeneration,
  - diabetic retinopathy or diabetic macular edema (complications of diabetes in the eye),
  - glaucoma (increase of intraocular pressure potentially leading to optic nerve damage),
  - retinal detachment, or
  - retinal vascular occlusions (problems with the blood vessels in your retina).

This is due to the possibility of a slight decrease in the level of retinal detail visible to your doctor during examination or treatment. Be sure to tell your eye doctor if you have been diagnosed with any eye disease.

Please discuss all risks and benefits with your eye doctor before your surgery.

### **Precautions**

- Before surgery, your eye doctor will check to see if you have any eye diseases or swelling. Be sure to tell your eye doctor if you have any health conditions (eg, breathing difficulties, heart trouble, allergies, previous eye surgery) that may affect your surgery or vision.
- You should avoid any activity that could harm your eye while you are recovering from surgery. Your eye doctor will tell you what activities you should avoid.
- Take all prescribed medicines and apply eye drops as instructed.
- The bag-like structure in your eye that your IOL is placed in may become cloudy after cataract surgery. If this condition develops, it may affect your vision earlier if you are implanted with the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0 compared to someone implanted with a standard monofocal IOL.
- The safety and effectiveness of the AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL have not been studied in patients with the following preexisting conditions:
  - Problems with your cornea (irregular shape of the cornea, previous corneal transplant, or diseases or conditions affecting the function of the cornea)
  - Problems with your eye anatomy (too little space in the front of the eye, no iris (the colored part of your eye), or eyes that are too small)

- Problems with your retina (Degenerative visual disorders (eg, macular degeneration or other retinal disorders), optic nerve damage, previous retinal detachment, or complications of diabetes in the eye)
- Other internal eye problems, for example, cataract due to German Measles or injury, recent inflammation inside the eye, new blood vessel growth in the iris, high pressure inside the eye (glaucoma), other pre-existing conditions that would cause the IOL not to be physically stable
- Lazy eye
- Color blindness or other color vision problems
- Previous refractive surgery such as LASIK
- Pregnancy

Other conditions not studied, that your doctor would be aware of include:

- When other ocular surgical procedures are planned for the time of cataract surgery
- When there is excessive movement of the iris during surgery
- When the dilated pupil is too small (less than 4.5 mm) during surgery
- When there is a requirement to use instruments to make the pupil larger during surgery
- When during surgery there is a significant loss of the jelly-like substance in the back of the eye, significant bleeding inside the eye, excessive pressure inside the eye, or complications affecting the physical stability of the IOL

You should tell your eye doctor of any eye problems or if you have been diagnosed with any eye condition.

### **Postoperative Care Instructions**

You will return home after surgery. Typically, your eye doctor will examine you the following day. Your eye doctor will give you eye drops to speed up the healing process and to prevent infection.

Your vision should improve within 4 to 6 weeks after cataract surgery. Many patients may see better within 1 to 2 weeks or less. The specifics of surgery may be different for each individual. Be sure to consult your eye doctor so you can fully understand the recovery process after the cataract surgery. It may take you some time to get accustomed to your new IOL(s). Always consult your eye doctor if you have any questions or concerns as a result of cataract surgery.

### **Key points to remember regarding your choice**

- Monofocal, multifocal, and accommodative IOLs can restore your vision following cataract surgery.
- It is important to discuss your lifestyle or visual needs with your eye doctor to help select the most suitable IOL for you.
- There is a greater chance of experiencing halos and glare with a Multifocal IOL as compared to a Monofocal IOL.

Thank you for considering the Alcon AcrySof® IQ ReSTOR® +2.5 D Multifocal IOL Model SV25T0.

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