PATIENT INFORMATION BROCHURE

AcrySof® IQ ReSTOR® +3.0 D
Multifocal Toric Intraocular Lens (IOL)

Models SND1T3, SND1T4, SND1T5, SND1T6

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AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric Intraocular Lens (IOL)

This brochure has been written to assist you and your surgeon to make 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 AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL (an IOL designed - to provide distance, intermediate, and near vision, as well as to correct astigmatism) would be a more appropriate choice compared to a standard monofocal IOL (an IOL designed to provide only distance vision).

What is an Intraocular Lens (IOL)?
An intraocular lens, commonly referred to as an IOL, is an artificial lens that is implanted in the eye to replace the natural lens when a cataract is removed. Below is a diagram showing the basic parts of the eye with an implanted IOL.

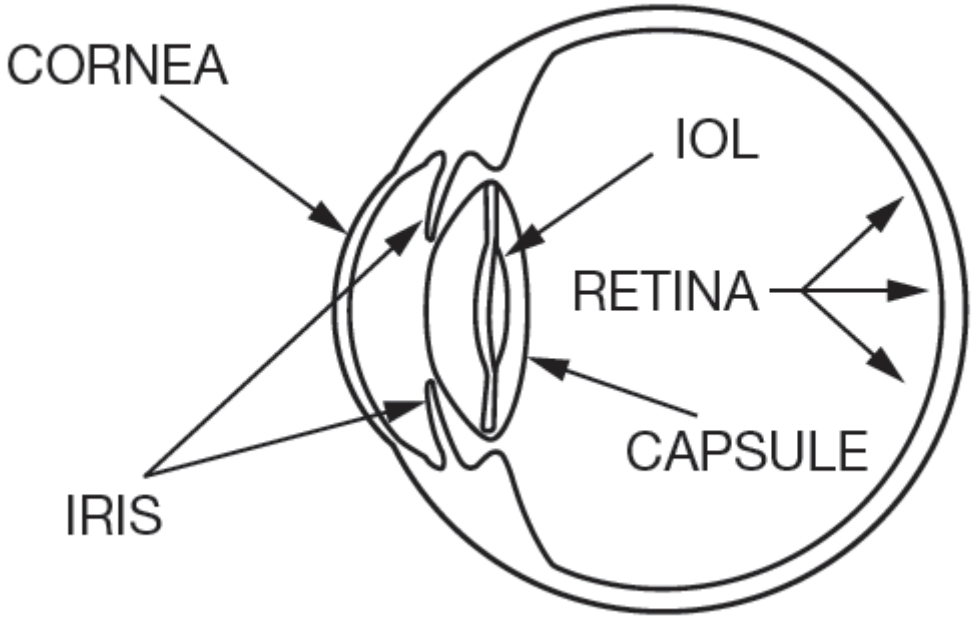

Figure 1 – Drawing of Eye with Implanted IOL

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.

A cataract can progress until eventually there is a complete loss of vision in your eye. 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 corneal astigmatism?
Astigmatism is a focusing error in the eye that results in blurred distance and/or near vision. In a normal eye, the cornea has a round shape (like a basketball); therefore, the light rays entering the eye focus at a single point on the back of the eye (retina) to form a clear image. In an eye with corneal astigmatism, the cornea has an oblong shape (like an American football). As a result, the light rays do not focus at the same point on the retina and parts of an object may not appear clear. During your eye examination, your eye doctor will be able to tell you if you have corneal astigmatism.

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 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 capsule. The capsule is located just behind the colored part of your eye (iris). A small incision is made in the outer surface of the eye to 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 act in the same way as your natural lens once did to focus images clearly onto the back of your eye (retina), to allow clear vision once again. 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. Surgery risks include reactions to medicines, bleeding, infection, inflammation, increased eye pressure and vision changes. Common side effects include redness, scratchiness of the eye, and light sensitivity. There is a small chance that your vision could be made worse by the operation, especially if bleeding or infection occurs. These risks are rare and may be outweighed by the potential benefits of restoring your vision. Please discuss these general risks associated with cataract surgery with your eye doctor.

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What types of IOLs are available for this procedure?
There are many different lOLs to choose from. Your eye doctor will discuss your options including this IOL and other IOLs.

In general, lOLs 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 edge of the optic. The haptics help maintain the location of the IOL in the eye. The basic IOL design allows for clear distance vision. Let's look at the basic ideas behind a standard (monofocal) IOL and the AcrySof® IQ ReSTOR® Multifocal Toric IOL.

AcrySof® Monofocal IOL
A monofocal IOL is designed to provide clear distance vision but does not optically correct corneal astigmatism. This means you will be able to see objects far away. However, you will most likely need glasses for near distance activities such as reading, writing, sewing as well as intermediate distance activities such as viewing a cell phone, applying makeup or shaving, working on a computer. Monofocal IOLs, like the AcrySof® Monofocal IOL, have been the standard monofocal implant used after a cataract is removed.

AcrySof® IQ Monofocal Toric IOL

A monofocal toric IOL is designed to provide clear distance vision and correct corneal astigmatism. There are different models of AcrySof® IQ Monofocal Toric IOLs for varying levels of corneal astigmatism. With an AcrySof® IQ Monofocal Toric IOL, you will be able to see objects far away. The AcrySof® IQ Monofocal Toric IOL, also, incorporates an aspheric surface designed to enhance distance vision under low light conditions, when a person wears full correction glasses. The lens is designed to benefit a person with an average corneal shape. However, you will most likely still need glasses for near distance activities such as reading, writing, sewing as well as intermediate distance activities such as viewing a cell phone, applying makeup or shaving or working on a computer.

AcrySof® IQ ReSTOR® Multifocal IOL
The design of the AcrySof® IQ ReSTOR® Multifocal IOL 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 than a monofocal lens would provide. There is a chance you may still need glasses for distance, intermediate, and/or near vision. This lens does not correct corneal astigmatism.

AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL
The design of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL allows for clear distance vision (watching children playing in the backyard) and correct corneal astigmatism. There are different models of AcrySof® IQ ReSTOR® Multifocal Toric IOLs for varying levels of corneal astigmatism. The center of the IOL also allows for better near (reading) and intermediate (computer work) vision than a monofocal lens would provide. There is a chance you may still need glasses for distance, intermediate, and/or near vision.

You will get the full benefit of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL 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 AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL
There are some side effects that can be associated with the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL including visual disturbances such as glare, rings around lights, and blurred vision. These side effects may make it more difficult to see while driving at night or completing tasks in low lighting such as at night or in fog, 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.

A toric IOL corrects astigmatism only when it is placed in the correct position in the eye. There is a possibility that the toric IOL could be placed incorrectly or could move within the eye. If the toric lens is not positioned correctly following surgery, the change in your astigmatism correction by the IOL, along with any necessary correction with glasses, may cause visual distortions. Also, if the lens rotates in your eye, you may need additional surgery to reposition or replace the IOL.

The table below shows the number of patients who reported severe visual disturbances with the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric lOLs and the control multifocal IOLs during a clinical study conducted in the United States.

Rates of Severe Visual Disturbances, 1 Year After Surgery

	Model SND1T3-T6 (Multifocal Toric)	Model SA60D3 (Multifocal)
	1 Year	1 Year
Halos (rings around lights)*	8 out of 100 patients	11 out of 100 patients
Glare (trouble seeing street signs due to bright light or oncoming headlights) *	4 out of 100 patients	3 out of 100 patients
Starbursts	4 out of 100 patients	9 out of 100 patients
Blurred Vision	1 out of 100 patients	0 patients
Hazy vision	1 out of 100 patients	1 out of 100 patients
Double vision	1 out of 100 patients	0 patients
Feeling sick due to visual distortion	0 patients	1 out of 100 patients
Color distortion	0 patients	0 patients
Distortion where flat lines look curved	0 patients	0 patients
Distortion where straight lines look tilted	0 patients	0 patients

* Any descriptions in parentheses were not provided to the patients in the study.

Warnings

- You may have some visual disturbances such as halos (circles around lights) or glare as compared to a standard monofocal IOL.
- You may not get the best results with a multifocal IOL if you have irregular astigmatism (if before surgery it is determined that the front surface of your eye is irregular in shape).
- It may be more difficult to see while driving at night or completing tasks in low lighting such as at night or in fog, after surgery as compared to before surgery.
- Contact your eye doctor immediately if you have any symptoms after surgery such as pain, itching, redness, watering of your eye or sensitivity to light.
- As with any surgical procedure, there is risk involved. These risks may include infection, retinal detachment or an increase in eye pressure.

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

Precautions

- The safety and effectiveness of the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL has not been established in patients with certain eye conditions, such as glaucoma or diabetic retinopathy (an increase in eye pressure or complications of diabetes in the eye). The outcome of cataract surgery will depend on the health of your eye before surgery. You should tell your eye doctor if you have been diagnosed as having amblyopia (lazy eye) or any other eye disease.
- 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 that may affect your surgery or vision.
- You should avoid any activity that could harm your eye while you are recovering from surgery.
- Take all prescribed medicines and apply eye drops as instructed.

- The capsule (bag-like structure) 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® +3.0 D Multifocal Toric IOL compared to someone implanted with a standard monofocal IOL.

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 almost always improves within 4 to 6 weeks. 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.

The AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL is designed to provide you with a full range of vision allowing you to see objects far away, up close, and in-between. It may take you some time to get accustomed to your new IOL(s). Always consult with your eye doctor if you have any questions or concerns as a result of cataract surgery.

Key points to remember regarding your choice:

- Both Monofocal and Multifocal IOLs can restore your vision following cataract surgery. However, the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL is designed to optically correct your corneal astigmatism and also to provide you with improved distance, intermediate and near vision.
- 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 chance of experiencing halos and glare with a Multifocal Toric IOL as compared to a Monofocal IOL.
- You may grow accustomed to the halos and glare or continue to notice them. If you drive a considerable amount at night, perhaps a monofocal IOL would be a better choice. Alcon offers a variety of monofocal and multifocal IOLs for your surgeon to choose from.

Thank you for considering the AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL.

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	Comparison of Study Results between AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric and AcrySof® ReSTOR® Multifocal IOLs at 1 year	
	AcrySof® IQ ReSTOR® +3.0 D Multifocal Toric IOL (Number of Patients=371)	**AcrySof® ReSTOR® Multifocal IOL (Number of Patients=180)**
Distance Vision without glasses in both eyes (driving, playing golf, etc.)	The majority of patients (96 out of 100) had good* distance vision.	The majority of patients (98 out of 100) had good* distance vision.
Distance Vision with glasses in both eyes (driving, playing golf, etc.)	The majority of patients (99 out of 100) had good* distance vision.	The majority of patients (99 out of 100) had good* distance vision.
Intermediate Vision without glasses (computer work, cooking, etc.)	A large number (86 out of 100) had acceptable** intermediate vision at approximately 23 inches (60 cm) and a large number (93 out of 100) of patients also had acceptable** vision at approximately 20 inches (50 cm).	A smaller number (47 out of 100) had acceptable** intermediate vision at approximately 23 inches (60 cm) and a smaller number (63 out of 100) of patients also had acceptable** vision at approximately 20 inches (50 cm).
Intermediate Vision with glasses in both eyes (computer work, cooking, etc.)	A large number (88 out of 100) had acceptable** intermediate vision at approximately 23 inches (60 cm) and a large number (97 out of 100) of patients also had acceptable** vision at approximately 21 inches (50 cm).	A smaller number (38 out of 100) had acceptable** intermediate vision at approximately 23 inches (60 cm) and a smaller number (67 out of 100) of patients also had acceptable** vision at approximately 21 inches (50 cm).
Near Vision without glasses in both eyes (reading, threading a needle, etc.)	The majority of the patients (96 out of 100) had acceptable** near vision at approximately 16 inches (40 cm).	The majority of the 92 out of 100 patients also had acceptable** vision at approximately 13 inches (33 cm).
Near Vision with glasses in both eyes (reading, threading a needle, etc.)	The majority of patients (98 out of 100) had acceptable** near vision at approximately 16 inches (40 cm).	The majority of the 97 out of 100 patients also had acceptable** vision at approximately 13 inches (33 cm).

* “good” vision is defined as 20/32 or better
** “acceptable” vision is defined as 20/40 or better