

# LABELING

## PHYSICIAN LABELING

**Caution: Federal Law restricts this device to sale by or on the order of a physician**

### Device Description

The eyeonics™ crystalens™ Model AT-45 Accommodating Posterior Chamber Intraocular Lens is a modified plate haptic lens with hinges across the plates adjacent to the optic.

### Indications for Use

The crystalens™ is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed and is intended to provide near, intermediate, and distance vision without spectacles. The crystalens™ provides approximately one diopter of monocular accommodation.

### Warnings

1. Some patients may still require glasses to perform certain tasks.
2. There is no clinical data to support placing this lens in the ciliary sulcus.
3. The safety and effectiveness of this lens have not been evaluated in patients under 50 years of age.
4. The effect of vitrectomy on accommodation is unknown.
5. Small amounts of lens decentration occurring with an IOL having a narrow or small optic (< 5.5 mm) may cause glare or other visual disturbances under certain lighting conditions. Surgeons should consider this potential complication before implanting an IOL with a small or narrow optic. This lens incorporates a 4.5 mm optic, the smallest IOL optic diameter currently available in the U.S.
6. YAG-laser posterior capsulotomies should be delayed until at least 12 weeks after the implant surgery. The posterior capsulotomy opening should be limited to no more than 4 mm. Consistent with other IOLS, there is an increased risk of lens dislocation and/or secondary surgical re-intervention with early or large YAG capsulotomies.
7. The crystalens™ should not be implanted if the capsular bag is not intact or if there is any zonular rupture.
8. The safety and effectiveness of the device has not been established in patients with the following ocular conditions:
  - a. chronic drug miosis
  - b. Amblyopia
  - c. diabetic retinopathy
  - d. previous corneal transplant
  - e. history of retinal detachment
  - f. congenital bilateral cataracts

- g. Recurrent anterior or posterior segment inflammation of unknown etiology, or any disease producing an inflammatory reaction in the eye.
- h. Patients in whom the intraocular lens may interfere with the ability to observe, diagnose or treat posterior segment diseases.
- i. Surgical difficulties at the time of intraocular lens implantation which might increase the potential for complications (e.g., persistent bleeding, significant vitreous prolapse or loss).
- j. Corneal endothelial dystrophy.
- k. Pseudoexfoliation syndrome.
- l. Suspected microbial infection.

Surgeons considering lens implantation in such patients should explore the potential risk/benefit ratio.

- 10. Mechanical hinge testing has been evaluated in a laboratory setting. Hinge movements of 1,000,000 cycles at 10 cycles per second have been documented with no degradation of hinge integrity or stability. However, long-term stability in the human eye has not been established. Therefore, surgeons should continue to monitor implant patients postoperatively on a regular basis.
- 11. The effectiveness of ultraviolet light absorbing lenses in reducing the incidence of retinal disorders has not been established. This lens does not significantly absorb light in the ultraviolet region. Patients should be informed that they should wear sunglasses with UV 400 protection when in sunlight.
- 12. The rate of cystoid macular edema may increase with sulcus-bag placement of the haptics.

### Precautions

- 1. Do not resterilize this intraocular lens by any method (See Returned Lens Policy).
- 2. Do not store lenses at temperatures over 45°C (113°F).
- 3. Do not implant this lens in the anterior chamber.
- 4. The crystalens will center automatically at the end of surgery. The optic should be vaulted backward to a position corresponding to the normal location of the posterior capsule. Attempts to position the lens further posteriorly by hyper-inflating the globe with BSS could lead to hyperopic outcomes and should be avoided.

### Adverse Events

The incidence of adverse events experienced during the clinical trial was comparable to or lower than the incidence reported in the historic control ("FDA grid") population (see Table 8). As with any surgical procedure, risk is involved. Potential complications accompanying cataract or implant surgery may include, but are not limited to, the following: lens subluxation, corneal endothelial damage, non-pigment precipitates, cystoid macular

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edema, infection, retinal detachment, vitreous loss, pupillary block, secondary glaucoma, iris prolapse, vitreous-wick syndrome, uveitis, and pupillary membrane.

### **Clinical Trial**

The US clinical trial of the crystalens™ Model AT-45 was conducted in 324 patients. The range of axial lengths studied in the clinical trial of the crystalens™ was 21.0 to 26.6 mm and the dioptric power range was 16.5 to 27.5 D. The clinical results were obtained using an 'A' Constant of 119.0, the SRK/T formula, immersion biometry or interferometry and manual keratometry.

### **Results**

The results achieved by 304 patients followed for one year provide the data that were used to support the conclusion that postoperatively, the majority of patients implanted with this lens achieve excellent near, intermediate, and distance vision without spectacles. Visual acuity with or without correction at all distances improves when both eyes are implanted with a crystalens™.

<b>1. In 124 bilaterally-implanted patients, the proportion of patients achieving uncorrected visual acuities of 20/32 (J2) or better at one year was:</b>			
<input type="checkbox"/> Distance	97.6%		
<input type="checkbox"/> Intermediate	100%	at 80 cm	
<input type="checkbox"/> Near	93.5%	at 40 cm	
<b>2. In the 74 bilaterally-implanted patients who were within <math>\pm 0.5</math> D of plano in each eye, the proportion of patients achieving uncorrected visual acuities of 20/32 (J2) or better at one year was:</b>			
<input type="checkbox"/> Distance	100%		
<input type="checkbox"/> Intermediate	100%	at 80 cm	
<input type="checkbox"/> Near	97.3%	at 40 cm	

The visual acuity and patient survey results are presented in Tables 2-7.

The stability of the outcomes was demonstrated in a consistent cohort of patients across the Form 3 to Form 4 (1-2 months to 3-6 months) and Form 4 to Form 5 (3-6 months to 11-15- months) postoperative intervals. Stability was measured using both the manifest spherical equivalent (MRSE) and visual acuity.

In a substudy comparing the crystalens™ with a control population comprised of several models of standard IOLs of varying types (e.g., single piece, multipiece) and materials (e.g., silicone, acrylic), the visual acuity at all distances at 3-6 months postoperative was significantly greater in crystalens™ implanted eyes than in eyes implanted with a standard IOL. The results are shown in Table 7.

## Detailed Device Description

### Lens Optic

- Material: Silicone Elastomer (Biosil™)
- Light transmittance: 95% ( $\pm 5\%$ ) in the visible region of the light spectrum (425-750 nm). UV cut-offs at 10% T for a +10 diopter lens (thinnest) and a +27 diopter lens (thickest) occurs at 350-355 nm as shown in Figure 1
- Index of refraction: 1.428 (35°C)
- Diopter power: +10 to +27 diopters in 0.5 diopter increments
- Biconvex optic diameter: 4.5 mm

### Haptics

The plate haptics have hinges across the face of the plates adjacent to the optic. Two flexible colored polyimide (Kapton™) loops are attached to each distal extremity of the plates, making the lens 11.5 mm in overall length. The length of the plate is 10.5 mm.

### Mechanism of action

The crystalens™ was designed to move in a backward and forward motion along the axis of the eye in response to pressure changes in the vitreous cavity and anterior chamber that result from relaxation and contraction of the ciliary muscle. The exact mechanism of action has not been fully elucidated.

### Directions for Use

1. Prior to implanting, examine the lens package for IOL type, power, and expiration date.
2. Open the peel pouch and remove the lens in a sterile environment.
3. Examine the lens thoroughly to ensure particles have not become attached to it, and examine the lens optical surface for other defects.
4. Position the lower blade of the forceps in the slot of the lens case beneath the lens. A standard intraocular lens forceps is recommended.
5. Grasp the lens so that the forceps extends across the *distal hinge* to stabilize the *leading plate haptic*.
6. Remove the lens in its position for implantation with a single grasp.
7. Advance the forceps through the incision to place the *leading plate haptic* of the lens into the distal capsular bag.
8. With a second instrument, hold the proximal *polyimide loop* to maintain position of the lens as the forceps are withdrawn.
9. Regrasp the tip of the *trailing plate haptic*. **Do not release the plate tip until the trailing haptic is placed into the capsular bag.**
10. As the *trailing plate haptic* is advanced into the anterior chamber, the *polyimide loops* will bend backwards on themselves as they traverse the small incision. The *leading plate haptic* will bend posteriorly at the hinge to a right angle deep into the back of the viscoelastic-filled bag.
11. Maintain the grasp at the tip of the *trailing plate haptic*. Tuck the *polyimide loops*, one by one, into the capsular bag. **Do not release the tip of the trailing plate haptic until insertion in the capsular bag is complete.**

12. Release and withdraw the forceps. The lens will self-center.
13. Once viscoelastic is removed, ensure that the lens is vaulted backwards against the posterior capsule to a position corresponding to the normal location of the posterior capsule before extraction of the cataract. **Do not hyper-inflate the globe.**

**NOTE:** The lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to its surface.

### **Lens Power Calculations**

The surgeon should determine preoperatively the power of the lens to be implanted. Lens power calculation methods are described in the following references:

- Holladay JT et al. A Three Part System for Refining Intraocular Lens Power Calculations. J Cataract Surg 14, January 1988.
- Retzlaff JA et al. Development of the SRK/T intraocular lens implant power calculation formula. J Cataract Refract Surg 16, May 1990.
- Hoffer KJ. The Hoffer Q Formula. A comparison of theoretical and regression formulas. J Cataract Refract Surg 19, November 1993.

NOTE: The Surgeon Factor, 'A' Constant and ACD values, which are located on the outside of the package, are estimates only. It is recommended that the surgeon determine his/her own values based on their individual clinical experience. Surgeons requiring additional information on lens power calculation may contact eyeonics.

### **Recommendations for Maximizing Patient Outcomes**

- The first eye implant should be targeted for -0.25 diopter and the second eye implant targeted for plano. In any case, the outcome of the second eye implant should be determined based on the outcome of the first eye.
- A single drop of 1% atropine must be administered immediately following surgery and 1 day after implantation.
- Incision size should be no larger than 4mm and a curvilinear capsulorhexis should be no larger than 5.5mm.
- Manual keratometry, immersion biometry or interferometry is strongly recommended to obtain optimum patient outcomes.
- A waiting period of two weeks between the first and second eye is recommended in order to accurately determine the lens power for the second eye.

### **Patient Registration Instructions and Reporting Registration**

Each patient who receives a crystalens™ must be registered with eyeonics™ at the time of lens implantation.

Registration is accomplished by completing the Implant Registration Card that is enclosed in the lens package and mailing it to eyeonics™. Patient registration is essential and will assist eyeonics™ in responding to adverse reaction reports and/or potentially sight-threatening complications. An implant identification card is supplied in the lens package and must be given to the patient.

### **Reporting**

Adverse Reactions and/or potentially sight-threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be reported to eyeonics™ at 866-eyeonics (393-6642) (USA). This information is being requested from all surgeons in order to document potential long-term effects of intraocular lens implantation.

### **How Supplied**

The contents of the inner and outer peel pouches are sterile unless the packages are damaged or opened. The intraocular lenses are moist heat sterilized and supplied in a lens case within a double aseptic transfer peel pouch. The contents of the inner and outer peel pouches are sterile unless the packages are damaged or opened.

### **Expiration Date**

Sterility is guaranteed unless the sterile pouch is damaged or opened. In addition, there is a sterility expiration date that is clearly indicated on the outside of the package. The lens should not be used after the indicated date.

### **Returned Lens Policy**

Please contact your local eyeonics™ office regarding lens exchange.

### **Bibliography**

1. Boettner, EA and Wolter JR 1962. Transmission of the ocular media. Invest Ophthal 1: 776-783.
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5. Cumming JS et al. Clinical evaluation of the Model AT-45 silicone accommodating intraocular lens. Ophthalmology 2001;108:2005-2010.

6. Cumming JS, Ritter J. The Measurement of Vitreous Cavity Length and its Comparison Pre- and Postoperatively. Eur J Implant Ref Surg 1994;6:261-272.
7. Fisher R. The ciliary body in accommodation. Tran Ophthalmol Soc UK 1986;105:208-219.
8. Girard LJ et al. Complications of the Simcoe Flexible Loop Phacoprosthesis in the anterior chamber. Ophthalmic Surg 14(4)
9. Glasser A and Kaufman PL. The mechanism of accommodation in primates. Ophthalmol 1999;106: 863-872.
10. Kammann J. Vitreous-stabilizing, single-piece, mini-loop, plate-haptic silicone intraocular lens. J Cataract Refract Surg 1998;24:98-106.
11. Thornton S. Accommodation in pseudophakia. Color Atlas of Lens Implantation. 1991;159-162.
12. Willis DA, Stewart RH, Kimbrough RL. Pupillary block associated with posterior chamber lenses. Ophthalmic Surg 1985; 16:108-9.

**Table 1**  
**crystalens™vs Standard IOL Distance Corrected Visual Acuity**  
**at All Distances (Distance, Near and Intermediate)**

	Crystalens™		Standard IOL	
	20/20 or better	1/121	0.8%	0/64
20/25 or better	29/121	24.0%	0/64	0.0%
20/32 or better	61/121	50.4%	3/64	4.7%
20/40 or better	107/121	88.4%	23/64	35.9%
Worse than 20/40	14/121	11.6%	41/64	64.1%

**Table 2**  
**Bilateral – Uncorrected Visual Acuity**

	Near at 40 cm		Intermediate at 80 cm		Distance	
	20/20 or better	39/124	31.5%	120/124	96.8%	98/123
20/25 or better	90/124	72.6%	122/124	98.4%	113/123	91.9%
20/32 or better	116/124	93.5%	124/124	100%	120/123	97.6%
20/40 or better	122/124	98.4%	124/124	100%	121/123	98.4%
Worse than 20/40	2/124	1.6%	0/124	0%	2/123	1.6%

**Table 3**  
**Bilateral – Uncorrected Visual Acuity for Patients Within  $\pm 0.5D$  of Plano in Each Eye**

	Near at 40 cm		Intermediate at 80 cm		Distance	
	20/20 or better	17/74	23.0%	--	--	67/74
20/25 or better	49/74	66.2%	74/74	100%	73/74	98.6%
20/32 or better	72/74	97.3%	74/74	100%	74/74	100%
20/40 or better	74/74	100%	74/74	100%	74/74	100%
Worse than 20/40	0/74	0%	0/74	0%	0/74	0%

**Table 4**  
**Unilateral – Uncorrected Visual Acuity (All Eyes)**

	Near at 40 cm		Intermediate at 80 cm		Distance	
	20/20 or better	52/368	14.1%	--	--	184/371
20/25 or better	161/368	43.8%	--	--	269/371	72.5%
20/32 or better	256/368	69.6%	--	--	311/371	83.8%
20/40 or better	328/368	89.1%	--	--	339/371	91.4%
Worse than 20/40	40/368	10.9%	--	--	32/371	8.6%

**Table 5**  
**Bilateral Patient Survey**  
**Activities Without Spectacles**  
**US Bilateral Subjects**

<b>Activity</b>	<b>Yes N/N (%)</b>	<b>No n/N (%)</b>
Perform most visual functions	120/128 (93.8%)	8/128 (6.3%)
Read most things	100/129 (77.5%)	29/129 (22.5%)
Go shopping	116/124 (93.5%)	8/124 (6.5%)
Participate in sports	84/87 (96.6%)	3/87 (3.4%)
Attend social gatherings	120/126 (95.2%)	6/126 (4.8%)
Drive	111/121 (91.7%)	10/121 (8.3%)
Read a newspaper	73/128 (57.0%)	55/128 (43.0%)
Sew or do needlework	35/91 (38.5%)	56/91 (61.5%)
Work on a computer	75/93 (80.6%)	18/93 (19.4%)
Do handy work around the house	119/126 (94.4%)	7/126 (5.6%)
Walk	126/129 (97.7%)	3/129 (2.3%)
Shop	117/128 (91.4%)	11/128 (8.6%)
Watch television	120/130 (92.3%)	10/130 (7.7%)

**Table 6  
Bilateral Patient Survey  
Difficulty With Night Activity  
US Bilateral Subjects**

<b>Symptoms</b>	<b>Absent N/N (%)</b>	<b>Mild N/N (%)</b>	<b>Moderate n/N (%)</b>	<b>Severe n/N (%)</b>
Night-time glare/flare	74/130 (56.9%)	31/130 (23.8%)	18/130 (13.8%)	7/130 (5.4%)
Night vision (difficulty driving at night)	82/121 (67.8%)	21/121 (17.4%)	14/121 (11.6%)	4/121 (3.3%)
Halos (rings around lights)	80/130 (61.5%)	26/130 (20.0%)	16/130 (12.3%)	8/130 (6.2%)

**Table 7  
Bilateral Patient Survey  
Wearing Spectacles During Waking Hours And to See At Night  
US Bilateral Subjects**

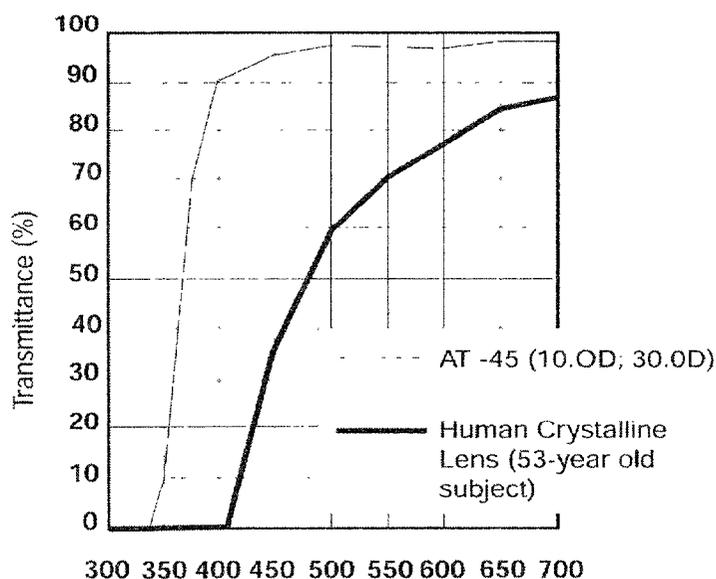
<b>Wearing Spectacles</b>	<b>n/N (%)</b>
<b>How often do you wear spectacles during waking hours?</b>	
I do not wear spectacles	33/128 (25.8%)
I wear spectacles almost none of the time (10%-25%)	61/128 (47.7%)
I wear spectacles some of the time (26%-50%)	20/128 (15.6%)
I wear spectacles most of the time (51%-75%)	8/128 (6.3%)
I wear spectacles all the time or almost all the time (76%-100%)	6/128 (4.7%)
<b>Do you wear spectacles to see at night?</b>	
No	110/130 (84.6%)
Yes	20/130 (15.4%)

**Table 8**  
**Adverse Events Reported at 12 months**

Adverse Event	Cumulative	FDA Grid	Persistent	FDA Grid
Endophthalmitis	1/324 (0.3%)	0.1%	----	----
Hyphema	1/324 (0.3%)	2.2%	----	----
Hypopyon	0/324	0.3%	----	----
IOL Dislocation	0/324	0.1%	----	----
Cystoid Macular Edema	12/324 (3.7%)	3.0%	2/304 (0.7%)	0.5%
Pupillary Block	0/324	0.1%	----	----
Retinal Detachment	0/324	0.3%	----	----
Secondary Surgical Reintervention	2/324 (0.6%)	0.8%	----	----
Corneal Edema	----		0/298	0.3%
Iritis	----		2/298 (0.7%)	0.3%
Raised IOP Requiring Treatment	----		0/304	0.4%

**Figure 1**

**SPECTRAL TRANSMITTANCE**  
(PERCENTAGE OF UV/VIS TRANSMITTED)



**Legend**  
**Curve 1:**

Spectral Transmittance (T) Curve Corresponding to the Central Region of the thinnest lens (+10 Diopter IOL). 10% UV cut-off is 350-355 nm.  
Spectral Transmittance (T) Curve Corresponding to the Central Region of the thickest lens (+27 Diopter IOL). 10% UV cut-off is 350-355 nm.

**Curve 2:** Spectral Transmittance (T) Curve Corresponding to a 53 year-old Phakic Eye.

**Note:** The spectral transmittance curves represent the range of transmittance values of IOLs made with this material.

SYMBOL	ENGLISH
	<b>MANUFACTURE DATE</b> (MM-YY: month-year)
	<b>DO NOT REUSE</b>
	<b>USE BY (MM-YY: month-year)</b>
	<b>SEE INSTRUCTIONS FOR USE</b>  <b>STERILIZED BY STEAM</b>

Manufactured in the USA: eyeonics inc., Aliso Viejo, CA 92656 USA (866) 393-6642

## PATIENT LABELING

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## **Introducing crystalens™**

Your physician has selected you as a good candidate for the crystalens™ accommodating intraocular lens.

Congratulations.

Crystalens Vision Enhancement System is completely unique. Unlike other mono- or multifocal IOLs, crystalens is dynamic within the eye, *moving continuously backward and forward* to bring images from various distances into sharp focus without glasses.

You may soon be able to focus your vision at near, intermediate and distant images as crystalens is designed to move effortlessly within your eye. For many, crystalens may diminish the need for glasses altogether.

This booklet will guide you through the process of receiving a crystalens from your doctor as treatment for your cataract. In addition, it will:

- Describe what a cataract is and your options to treat it
- Provide a good understanding of the crystalens accommodating intraocular lens
- Explain the procedure
- Let you know what to expect from the crystalens and how to get the best result
- Review the clinical results and the experiences of others
- Answer other questions you may have

Please consult with your doctor concerning any questions you have about the crystalens or the surgery. You can also obtain additional information by calling the manufacturer, eyeonics, toll-free at 866-eyeonics (393-6642).

## **What is a cataract**

Cataracts are a natural part of the aging process. More than 20 million Americans have cataracts.

A cataract is a progressive thickening, hardening and clouding of the eye's lens. Because cataracts develop very slowly, the decline in vision can be difficult to detect. The first sign that your lens is hardening may be an increasing need for reading glasses. This is due to a loss of accommodation, the ability of the eye's lens to move back and forward to focus on images that are near (14 inches or closer), intermediate (14 to 36 inches from the viewer) and distance.

**Near vision** is utilized for images such as reading, sewing or putting on makeup.

You use your distance vision when taking a walk or window-shopping.

**Intermediate vision** encompasses most daily activities, such as working on your computer or checking the instruments on your dashboard when driving.

Loss of accommodation, also known as presbyopia, affects nearly everyone after age 40. It actually begins gradually at about age 10 and continues to decline, becoming noticeable when we begin to experience difficulty focusing on close objects or fine print.

When this occurs, most people purchase reading glasses for occasional use. As the condition progresses, many people find they own several pairs and experience increased frustration at their growing dependence on them for daily life.

When one is old enough to develop cataracts, they may affect your ability to enjoy the things you used to do. In addition, you may experience changes in how you see colors, have problems with glare from lamps or the sun, begin to encounter double vision or see a frequent need for a new, stronger spectacles prescription.

Eventually, your physician will recommend cataract surgery, the most common and one of the safest procedures performed in the U.S. Removal of the opacified lens and replacement with an artificial lens (an intraocular lens implant or, rarely, aphakic glasses) is the primary treatment for cataracts.

((Consider as boxed copy))

((Illustration of eye))

## **How the eye works**

### **CORNEA**

The transparent front segment of the eye that covers the iris and the pupil, providing most of the eye's optical power.

### **IRIS**

Pigmented tissue that lies behind the cornea that gives color to the eye (e.g., brown eyes) and controls the amount of light entering the eye by varying the size of the black pupillary opening. The iris opens wide for distance vision and constricts for near vision.

### **CRYSTALLINE LENS**

The natural crystalline lens is the primary focusing mechanism of the eye. Made up of protein and water, located behind the iris, it changes shape and moves forward and back to focus images from various distances onto the retina.

### **CAPSULAR BAG**

The clear, thin, elastic membrane that holds the lens. When a cataract is removed, the replacement IOL is implanted into the capsular bag.

### **ZONULES**

Thin fibers that ensure the stability of the lens, attaching it to the ciliary muscle.

### **CILIARY MUSCLE**

Controls the accommodation of the lens. When the muscle relaxes, the lens rests in the back position for distance vision. When the muscle contracts, it pushes down on the vitreous, which gently pushes the lens forward for near vision. As the lens enlarges and hardens, the ciliary muscle is unable to work as well.

### **VITREOUS HUMOR**

A transparent jelly and fluid that fills the section of the eye between the retina and the lens. When the ciliary muscle contracts, the vitreous gently pushes the lens forward.

### **RETINA**

Sensitive tissue at the rear of the eye that contains the light sensitive rods and cones that capture the visual images and sends them along the optic nerve to the brain.

### **OPTIC NERVE**

Carries the visual information captured on the retina to the visual cortex of the brain for recognition and interpretation.

## **Vision Restoration Options**

Until now, all options for treating early loss of accommodation were fixed focus (stationary) solutions such as glasses, contact lenses or bifocals.

After the cataract matured, the natural cataractous lens is surgically replaced with an artificial lens implant called an intraocular lens or IOL. While IOLs are a proven option for the treatment of cataracts, they too are stationary within the eye.

### **Intraocular Lens Implants (IOLs)**

Until now, there have been two types of IOLs, monofocal and multifocal.

#### **Monofocal IOLS**

The vast majority of available IOLs are monofocal. It is a technology that has been used successfully for decades. Monofocal IOLs provide clear vision at one focal point, usually distance vision. In most cases, however, the patient still needs to wear glasses or contact lenses to see images within their near field of vision and sometimes for those in the intermediate field of vision, as well.

#### **Multifocal IOLS**

Multifocal IOLs are a relatively new technology. Different fixed visual zones are built into the optic of the lens. Multifocal IOLs can be a good option for the right patient, although patients with multifocal IOLs have reported problems with glare and halos.

### **Corneal Ablation (LASIK, LASEK and PRK)**

LASIK and other corneal procedures re-shape the cornea to correct nearsightedness, farsightedness or astigmatism. None of those procedures address accommodation or cataracts in any way. Most doctors feel these types of procedures are a good option for younger patients who have not begun to experience loss of accommodation.

((Consider box copy and visual, line art demonstrating need for continuous range))

((HEADLINE))

### **Without accommodation, all other options fall short**

Patients cannot adjust their vision from distance to intermediate and near.

### **The challenge of stationary vision**

Accommodation allows the eye to continually and effortlessly focus on all images within the viewer's *total* range of vision. Because the ciliary muscle is able to adequately contract, the vitreous can gently push the lens forward to provide a continuous range of vision.

With accommodation, there is no need to stop, find and put artificial fixed focal points (glasses or bi-focals) into place. In fact, the movement of putting glasses on and off--and/or moving your eyes between the dual focal points of your bifocals—is a substitute for the loss of accommodation.

### **Introducing crystalens accommodating IOL Addressing cataracts through the power of accommodation.**

((Insert graphic of lens with call-outs))

The crystalens accommodating intraocular lens

- Plate Haptics and loops hold the lens in place
- Hinges allow lens to move gently forward and back
- Optic focuses the image on the retina

((Insert new illustrations of lens working in eye))

Captions from crystalens brochure to come

Crystalens is the first and only accommodating IOL in the United States.

Crystalens is designed to mimic the natural accommodating process of the eye. The exact mechanism of the lens has not yet been confirmed but it is designed to move backward and forward inside the eye using a hinge, which is located next to the optic of the lens. The effect on the hinge for movement of greater than a million cycles has not been established. This dynamic enables the eye to automatically focus the lens on images that are within distant, intermediate and near fields of vision and eliminates or reduces your need for glasses or contact lenses after surgery. Remember, while there is every reason to believe you will receive excellent results from your crystalens, everyone's focusing capabilities are different. Your optimal vision solution may allow you to do most things without glasses while others may be more comfortable with spectacles for a certain task.

## **Excellent visual results**

The crystalens clinical study for the United States Food and Drug Administration involved 497 eyes in 324 adult patients over 50 years of age. Results of the study demonstrated crystalens power to restore patients' vision and reconnect them with the most important aspects of their lives.

- 100% of patients implanted with crystalens in both eyes could pass a driver's test without their glasses
- 100% could see intermediate (24" to 30"), the distance for most of life's daily activities, e.g., dashboard, prices in the supermarket, and their computer screen, without their glasses
- 98.4% could see well enough to read print the size of the stock quotes in the newspaper or read the phone numbers in the white pages of a telephone book without their glasses
- More than 80% reported they were using their computer, shopping and applying make-up without needing their glasses
- Some patients did require glasses for some tasks after implantation of the crystalens
- Significantly more patients implanted with a crystalens (88.4%) could see better at all distances than patients implanted with a standard IOL (35.9%).

((Insert series of near, intermediate and distance images. Contrast sensitivity – show the clear images, defined, no halos. Show images of the muted colors and bright colors – same changes as would see with typical IOL))

### Clinical study results

#### Benefits:

The crystalens clinical study involved nearly 500 eyes in more than 300 patients. The results indicated that almost all of the patients implanted in both eyes with the crystalens had good distance vision after surgery (i.e., they could see 20/32 or better at distance), all patients had good intermediate vision, which means that they could see a computer screen or items at arms length, and the majority (98.4%) could read the newspaper without glasses. Almost all of the study patients had vision good enough to allow them to pass their drivers test, see their computer, shop, apply their makeup, or read a newspaper without glasses or contact lenses. Of those patients who had only one eye implanted, about 1 in 10 had their near and/or far vision worse than 20/40 after the surgery. Two in a hundred had their intermediate vision become worse than 20/40 after the surgery. In contrast, of those patients implanted with a standard IOL, about 6 in 10 had their near and/or far vision worse than 20/40 after the surgery. Six in a hundred had their intermediate vision become worse than 20/40 after the surgery.

In the clinical study, more than 85% of patients were able to drive with mild to no difficulty at night. In addition, nearly 85% of patients did not wear spectacles to see at night.

**Risks:**

The complications and side effects experienced during the clinical study were similar to those experienced with other intraocular lenses and with routine cataract surgery. Because it is surgery it is not completely risk-free. Complications may occur as a result of the removal of your cataract whether or not an intraocular lens is implanted.

Complications of cataract surgery range from minor, usually temporary side effects, to sight-threatening complications. Fortunately, significant sight-threatening complications are extremely rare and include, but are not limited to infection, hemorrhage, and retinal detachment. People with existing medical conditions such as diabetes and chronic eye infections are at a higher risk of developing complications.

The risks of implantation with the crystalens are the same risks that exist for all intraocular lenses. However, because the crystalens works by moving forward and backward in the eye, there is a risk of the lens becoming stuck in the forward position, giving you only good near vision. In this case, you will need spectacles or contact lenses to see at distance. If the lens becomes stuck in the backward position, it will give you good distance vision, like a standard intraocular lens, but you will need spectacles to read or to see near objects. None of the patients in the clinical trial had their lenses stick in either the forward or backward position during the 12 months of the study.

The effectiveness of ultraviolet light absorbing lenses in reducing the incidence of retinal disorders has not been established. Unlike your crystalline lens and most IOLs that are currently available in the United States, the crystalens does not absorb a significant amount of ultraviolet light. Therefore, you should wear sunglasses with UV 400 protection when in sunlight.

The long term safety and effectiveness of this lens have not been proven.

**Are you a candidate for the crystalens?**

Your doctor will perform a thorough examination to determine if you have a cataract, and advise you of the most appropriate option for correcting your vision. Depending upon your expectations, lifestyle and the presence of any pre-existing visual conditions, your ophthalmologist will determine whether you can benefit from the implantation of a crystalens IOL.

Virtually everyone with good general health is a candidate for implant surgery. Individuals with chronic eye infections, uncontrolled diabetes, or other health problems may have to wait until these conditions are managed before they have surgery.

People who have had prior corneal refractive surgery (for example, LASIK) are acceptable candidates for crystalens implantation as long as their eye is in good health.

If you have already had cataract surgery, you are not a candidate for crystalens implantation.

## What to Expect

### Before Surgery

Once selected as a candidate for the crystalens, be certain that you are comfortable with all aspects of your cataract surgery. Ask questions and inform your surgeon of any medications you are currently taking. Prior to surgery, you can expect:

- Pre-op visit- physician evaluations of your eye and vision needs  
*This is your chance to ask questions of your doctor and share any specific visual needs you might have. For example, if you have a hobby or pastime, such as oil painting, golfing, playing the piano or gardening.*
- Precise pre-op measurements  
*Prior to surgery, your doctor will perform three tests that will measure your vision and help to ensure the results achieved by your crystalens are consistent with your expectations.*
  - *Refraction-measures what you see compared to a standard scale, i.e. 20/20*
  - *Biometry-measures the length of the eye and tells the doctor the power of the lens to be placed in the eye*
  - *Keratometry-measures the amount your cornea is curved, bending light toward your lens*

### During Surgery

While crystalens is a unique technology, your doctor has performed hundreds of surgeries with very similar requirements and undergone additional training for achieving the best outcomes with crystalens. The expertise of your doctor is well matched to the innovations offered by the crystalens. That is why he or she was selected to offer the crystalens to patients.

A few things to know for your day of surgery:

- Surgery with the crystalens is an outpatient procedure  
*Surgery is usually performed as an outpatient procedure and typically takes less than 20 minutes. However, you will need a friend or family member to take you home.*
- Your surgeon will use eye drops to anesthetize your eye and dilate your pupil
- Your nurse will cleanse and drape your eye
- You will be awake during the short procedure
- You will experience no pain, but there will be a slight pressure

## Getting the best result

### After Surgery

It is important that you closely follow your doctor's instructions after surgery with the crystalens. Do not rub your eye since this could impair its healing. During the first day post-op it will be important to limit your activity. After that you should be able to perform all of your normal activities, including showering and swimming. In addition, during the first two weeks it is important to remember:

- Use glasses to read while your new lens *settles* within your eye
- Your pupils will be dilated, so you will not be able to focus near and you may experience glare
- Your intermediate vision will be slightly diminished, but will improve
- Your distance vision will not significantly diminish and will improve
- You may experience halos around bright lights because of the eye drops your doctor has given you. These side effects will quickly dissipate

### AFTER TWO WEEKS, READ WITHOUT YOUR GLASSES AT LEAST TWICE A DAY FOR 10 MINUTES A SESSION.

Read the smallest type you are comfortable with. A Vision Restoration Card may be provided as a tool in re-training your eye muscles.

Among the most important things post-operatively will be for you to work the ciliary muscle back into shape. This is the muscle in your eye that enables your natural lens to move to focus on images at different distances. As part of the normal aging process, it has not had to work as it did when you were younger since you have seen at near through a bifocal or reading glasses. That is because your own lens has enlarged and hardened and become less flexible. Therefore, the muscle surrounding that lens is out of shape and must be exercised back into shape.

To achieve that end:

- Don't wear any reading glasses after the first two weeks
- Use the Vision Restoration Chart daily
- READ, READ, READ without glasses
- Keep practicing until you can read comfortably without glasses (may be approx. 2 months but will probably improve over the first 12 months)
- You should wear sunglasses with UV 400 protection when in sunlight

And, remember:

- Your near vision may continue to improve for up to 12 months, especially if you use it!!

## **Frequently Asked Questions**

- **What is crystalens?**

crystalens is a new technology that is designed to mimic the eye's natural ability to focus on distant, intermediate and near objects. Used in conjunction with standard cataract extraction methods, the crystalens can restore a continuous range of vision without total dependence on glasses or contact lenses.

### **What makes the crystalens different from other intraocular lenses?**

The crystalens has the unique ability to focus on objects at varying distances using the eye's natural muscle. This means that the crystalens can provide improved vision, without corrective lenses, throughout a range of distances from near to far.

Standard (single vision) lens implants have a single focus point and do not have the ability to provide a full range of vision. Most people who have single vision lens implants MUST wear glasses for intermediate and near vision.

### **Can my vision be corrected to 20/20, for both reading & distance?**

In the clinical studies with 324 patients over the age of 50, 100% could see images at intermediate distances (24"-36"), 98.4% could read print the size of the stock quotes in the newspaper or phone numbers in the telephone book and 98.4% could see distant objects all without glasses. 100% could see well enough without their glasses to pass their driver's test. It was also shown in the clinical studies that significantly more patients implanted with a crystalens (88.4%) could see better at all distances than patients implanted with a standard IOL (35.9%).

Visual acuity is subjective and depends upon each individual's own ocular and physiological conditions as well as lifestyle preferences. Some patients implanted with the crystalens still require glasses for certain activities.

### **What about my intermediate vision, like working on the computer. Will it be like wearing trifocals?**

Your ability to see at approximately arm's length (intermediate vision) will be greatly enhanced with the crystalens. Over 98% of people enrolled in the clinical study were able to see 20/20 at arm's length without correction. And, 100% could see 20/32.

In addition, the quality of vision compared to wearing trifocals is significantly improved. You can have a continuous range of vision, without having to tilt your head to find that portion of your glasses that allows you to see clearly. The crystalens is designed to mimic the natural focusing ability of your eye.

### **Will I be able to read in all light conditions?**

The crystalens functions very much like the normal human lens. It is important to remember that reading vision in low light is also influenced by the overall health of your eye and by the condition of the light sensors in the retina. As we get older our ability to see in low light conditions may start to decrease. It is always best to read in good light conditions.

### **How do I know if I am a good candidate for crystalens implantation?**

If your vision is becoming less clear, you suspect you have a cataract or if you are frustrated with an increasing dependence upon glasses, you should consult with your ophthalmologist. Your doctor will perform a thorough examination and advise you of a customized treatment plan for effectively correcting your vision.

Virtually everyone with good general health is a candidate for implant surgery, but people with chronic eye infections, uncontrolled diabetes, or other health problems may have to wait until these conditions are under control prior to surgery.

People who have had prior corneal refractive surgery are acceptable candidates for crystalens implantation as long as their eye is in good health. Talk to your doctor.

If you have already had cataract surgery, you are not a candidate for crystalens implantation.

### **How long with the surgery take? Will I feel anything?**

Crystalens implant surgery is typically performed in an outpatient surgical facility. You will arrive at the surgery center about an hour before the procedure. A number of drops will be placed in your eye and oral medications may be administered to help you relax. The eye drops anesthetize your eye and dilate your pupil.

The actual surgery usually takes less than 15 to 20 minutes. The surgeon will stabilize your eye with a device to keep your eyelids open. You will feel no pain, only slight pressure on your eye.

### **What can I expect after surgery?**

Once the surgery is complete, additional drops will be placed in your eye to prevent infection, decrease inflammation, and keep your pupil dilated. A patch may be placed over your eye and someone will need to drive you home. Once at home, you should rest for the remainder of the day. You should avoid any strenuous activities. Your

doctor will see you the day after surgery to remove the eye patch, if used, and examine your eye. Do not rub your eye since this could impair healing.

The doctor will give you additional medications that you will need to put in your eye for the next two weeks. These drugs help the eye heal and will wear off in a week to 10 days leaving no residual effects.

**What are the chances that something could go wrong with the surgery?  
What would they be?**

Cataract surgery is one of the most common eye procedures currently performed and is considered to be extremely safe and effective. The risk of sight-threatening complication is extremely rare, but because it is surgery it is not completely risk-free.

Complications of cataract surgery range from minor, usually temporary side effects, to sight-threatening complications. Fortunately, significant sight-threatening complications are very rare and include, but are not limited to infection, hemorrhage, and retinal detachment. People with existing medical conditions such as diabetes and chronic eye infections are at a higher risk of developing complications.

Your doctor will perform a thorough examination and fully inform you of any increased risk of a complication.

**What will my vision be like after surgery?**

Your distance vision will usually be very good within a day or two after surgery. However, your middle and near vision may be somewhat blurred at first.

Drops will be applied to your eye after surgery, which paralyze the eye's ability to change the focus from far to near. These drops dilate your pupil and may make you sensitive to light until the drops wear off. This is done to ensure that the crystalline lens is correctly positioned in your eye as it heals. It will take 7 to 14 days for the effects of this drug to wear off. You may need to wear reading glasses to help you read during this time.

After about 2 weeks, you may notice that your intermediate (arm's length) vision is improving and your near vision is also starting to get better. It is important that you discontinue the use of the reading glasses at this time so that you strengthen the focusing muscle of your eyes.

It may take several months for your eyes to reach their full focusing potential. The more you try to read without reading glasses, the quicker you will be able to read without them. You may notice a difference in your vision from one eye to the other after your eyes heal. This is normal. If the difference in your vision is significant your doctor may recommend additional surgery, although this is rare. This is often done for the correction of astigmatism after implant surgery.

Everyone's focusing ability is different. Most people will be able to see clearly in the distance, have excellent intermediate vision and will be able to read a newspaper without glasses, but some people may be more comfortable with additional correction, particularly at night or in dim light.

It is important to remember that implant surgery cannot resolve pre-existing visual conditions such as floaters, flashes, macular degeneration, or visual field loss that are a result of conditions of the eye and are not related to the human lens.

**What about glare, problems driving at night and sensitivity to light? Can implant surgery create these problems?**

These symptoms can be produced or exacerbated by cataract surgery. A unique feature of the crystalens is the smaller optic (4.5 mm diameter) compared to a standard IOL which is typically 6.0 mm in diameter. Many people report these problems before cataract surgery and even after surgery; however, they are rarely debilitating. While clinical studies showed that the amount of glare experienced by patients implanted with the crystalens was comparable to a standard IOL and is minimal to absent, small optics may cause glare or other visual disturbances under certain lighting conditions.

Glare can be a problem at night when the pupil widely dilates. This typically does not occur in your central field of vision, but rather in the periphery.

**Will I have to have cataract surgery again?**

Once your cataracts are removed and replaced with an artificial lens, you will never have to have cataract surgery again. Occasionally, several months after the lens has been placed in the eye, the vision may start to become cloudy once again. This is sometimes called a secondary cataract and refers to the clouding of the membrane that surrounds the implant.

A laser is used to make an opening in the membrane behind the implant, immediately improving vision. This is usually done in the office and takes only a few minutes and does not require an anesthetic. Once this is done no further surgery related to your cataracts will be required. This procedure is known as a YAG capsulotomy.

**How do I know who is a qualified crystalens implant surgeon?**

All surgeons who are implanting the crystalens have gone through a comprehensive training course. Your surgeon has been performing cataract implant surgery for years and applies many of the same techniques to implanting the crystalens.

## **Glossary of Terms**

**Accommodation** - The movement of the lens to focus on images at various distances.

**Anesthesia For Cataract Surgery** - The standard cataract surgery anesthetic is now topical drops. The patient is awake during surgery, but may be sedated.

**Aphakia** - The absence of the eye's natural crystalline lens, usually after cataract removal.

**Aphakic Spectacles** - Thick, plus-powered eyeglasses that were once the standard correction following extraction of a cataract. The glasses were cumbersome and greatly distorted peripheral vision. Today, an intraocular lens (IOL) is implanted in the eye after the cataractous lens is removed.

**Astigmatism** - Astigmatism is blurry vision produced by football-shaped corneas, which are too steep in one place and too flat in another. Astigmatic corneas focus light in two different places in the eye, making both near and distance vision a problem.

**Capsular Bag** - The clear, thin, elastic membrane that holds the lens.

**Cataract** - An opacity or clouding and hardening of the crystalline lens that may prevent a clear image from forming on the retina and reduces the lens' ability to accommodate. The cataractous lens may require surgical removal and replacement with an intraocular lens if visual loss becomes significant.

**Ciliary Muscle** - Control the accommodation of the lens. When the muscle relaxes, the lens rests in the backwards position for distance vision. When it contracts, it increases the pressure in the vitreous which gently pushes the lens forward for near vision. As the lens enlarges and hardens, the ciliary muscle is unable to work as well.

**Cornea** - The transparent front segment of the eye that covers the iris and pupil, providing most of the eye's optical power.

**Crystalline Lens** - The natural lens of the eye, located behind the pupil, which helps bring rays of light to focus on the retina. Made primarily of protein and water, the original state of the lens is transparent and flexible, but the lens becomes cloudy, enlarges and hardens with age.

**Diopter** - A measurement of the degree to which light converges or diverges; which relates to therefractive power or strength of the lens.

**Haptics** - The two plates and/or tiny loops located on opposite sides of an intraocular lens that hold the lens securely in place. crystalens has patented hinges built into the haptics to allow gentle movement forward and backward to focus.

**Hyperopia** - Also known as farsightedness, hyperopia is a refractive error caused by the eye being too short. Light focuses behind the retina and therefore strikes the retina before it can come to a sharp focus.

**Intermediate Vision** - Range of visual focus between 14" - 36", e.g., seeing the dashboard, prices in the supermarket, computer screen

**Intraocular Lens (Iol)** - A clear, artificial lens that may be surgically implanted to replace the natural cataractous lens of the eye. The crystalens is a flexible IOL made of a proprietary advanced generation solid silicone called BioSil™.

**Iris** – The pigmented tissue that lies behind the cornea that gives color to the eye (e.g., brown eyes). It controls the amount of light entering the eye by varying the size of the black pupillary opening. The muscles in your iris open the pupil wide for distance vision and make it small for near vision.

**Laser Assisted In-Situ Keratomileusis (Lasik)** - Is considered effective for myopia (nearsightedness). The surgeon uses an excimer laser to ablate a thin layer of the cornea. LASIK will not treat a cataract or improve the lens' ability to accommodate.

**Myopia** - Also known as nearsightedness, myopia is a refractive error caused by the eye being too long. In these cases light focuses instead in front of the retina.

**Near Vision** - Range of visual focus up to 14", e.g., reading, sewing, etc.

**Ophthalmologist** - A physician and surgeon specializing in refractive, medical, and surgical treatment of eye diseases and disorders.

**Optometrist** – A primary eye care provider who diagnoses and treats disorders of the visual system, and manages and treats eye diseases.

**Phacoemulsification** (fay-koh-ee-mul-sih-fih-KAY-shun) - A cataract surgical procedure which uses an ultrasonic vibration to break up and remove a cataract through a tiny incision.

**Point Size** - A relative measure of the size of a font in type. 20/40 vision is equivalent to reading 6-point type, the size of the stock quotes in the newspaper or print in the telephone book. Most computers are set to 12-point type.

**Presbyopia** - Occurs as the lens of the eye ages, enlarges and becomes less elastic and less able to accommodate. Usually becomes significant after age 45 and is often signaled by the need for reading glasses or bifocals.

**Pupil** - The variable-sized, black circular opening in the center of the iris that controls the amount of light that enters the eye.

**Retina** - The thin lining at the back of the eye that converts images from the eye's optical system into electronic impulses sent along the optic nerve for transmission to the brain.

**Vitreous Humor** - A transparent jelly and fluid that fills the section of the eye between the retina and the lens. When the ciliary muscle contracts, it increases the pressure in the vitreous which then gently pushes the lens forward.

**Yag Laser** - The YAG laser is a surgical instrument that emits a short pulsed, high energy light beam that can be precisely focused to treat clouding of the remaining capsular tissue that envelopes the IOL. The surgery is performed on an outpatient basis, is done without an anesthetic usually in the office, takes only a few minutes and is painless.

**Zonules** - Thin fibers that attach the lens to the ciliary muscle.

((Full footprint))