

OPERATOR MANUAL

The IOL Counselor™ Operator Manual

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SECTION I: INTRODUCTION TO THE IOL COUNSELOR

The increasing number of presbyopia correcting IOLs available to today's lens implant candidates requires considerably more time and effort to explain their advantages and disadvantages over traditional monofocal IOLs. Many patients are unable to focus their attention on understanding their IOL options at the time of cataract diagnosis, as they are distracted by the fear generated from knowing their eyesight may be at risk and how to fit cataract surgery into their busy schedules.

Industry sources suggest that the current conversion rate from a conventional monofocal IOL to a premium-priced IOL is very low, in most cataract practices. The majority of surgical counselors in these low conversion practices report that the higher cost of the procedure and lenses simply makes it impossible for seniors on fixed incomes to afford. However, as with any luxury item, consumers are going to be reluctant to purchase until they fully understand the benefits of the item and are led through the decision-making process by an accomplished salesperson. The IOL CounselorTM was created to dramatically increase the probability of your patients' selecting a presbyopia correcting IOL and to minimize the amount of time doctors and surgical counselors need to demonstrate and explain their IOL options.

The IOL CounselorTM is not a tool to facilitate informed consent. It is not possible to create simulations that will represent exactly how a patient will see with any IOL. The clarity and quality of how they will see in various lighting conditions depend on the optical characteristics of the specific IOL, along with many individual factors such as surgical over- or undercorrection, individual healing characteristics, preexisting astigmatism, pupil size, and the overall health of their eye.

Components

The IOL CounselorTM represents a systematized approach to explaining the costs and benefits of presbyopic IOLs. Its step-by-step approach to explaining the physician's recommended IOL is easy to master by most patient counselors, regardless of their level of salesmanship.

The IOL CounselorTM consists of six elements:

Dr. Steven Dell's Vision Assessment Questionnaire

The IOL CounselorTM Software

The IOL Acceptance Form

An Overview Patient Education Video

A Tutorial Video to Train Counselors

A Tutorial Video to Explain How to Activate the IOL CounselorTM

Vision Assessment Questionnaire

Originally produced by Stephen Dell, M.D., of Austin, Texas, the Vision Assessment Questionnaire will help your doctor prescribe the most appropriate IOL for each patient. Based on patient responses concerning lifestyle issues and their preference for clear vision within five zones of vision, your doctor will circle an IOL recommendation, hand it back to the patient with some discussion regarding the recommendation, and send the patient with the Vision Assessment Questionnaire over to the surgical counselor.

*The IOL Counselor*TM *Software*

The heart of The IOL Counselor™ is its multilayered software application that contains a comprehensive series of animations, designed to help the doctor or surgical counselor explain presbyopia, cataracts, cataract surgery, monofocal IOLs, and presbyopia correcting IOLs.

The IOL Acceptance Form

After explaining IOL options, each patient must sign the IOL Acceptance Form, indicating which IOL they want for their surgery. If they choose a standard or aspheric monofocal IOL, they must check a box indicating they are aware that their dependence on glasses will be greater with the monofocal IOL than it would be if they chose not to upgrade to a presbyopic correcting IOL. It also documents that they understand that the simulations they saw with the IOL CounselorTM were not shown as a guarantee as to how they will see postoperatively.

Patient Flow Through

There are numerous ways to incorporate the IOL Counselor™ into your patient flow. The goal is to minimize the amount of time the doctor spends with each potential candidate for a presbyopia correcting IOL, while helping them make an IOL recommendation. The following step-by-step process may need to be modified within your practice; however, we suggest you try it for a while to see if your practice can adapt to it, rather than it adapting to your practice.

Step #1: Upon check-in, the receptionist hands each patient over the age of 55 a Vision Assessment Questionnaire form to complete, while they wait to see the doctor. They are told to give it to the doctor after the examination. Obviously, if they are in for a routine check-up or follow-up care for another existing condition, or if they had already completed one the last time they were in, they would not get one. However, if they are presenting with cataract symptoms, responding to advertisements about presbyopic IOLs, or coming in as a cataract referral, you would want them to fill out a form. Having this completed prior to diagnosis will dramatically speed the counseling and decision-making process.

Step #2: After determining that the patient has a cataract or is a candidate for lens implant surgery, the doctor quickly reviews the Vision Assessment Questionnaire form and selects one of the IOLs at the bottom of the form.

Step #3: After reviewing the answers and determining the importance of the various zones of vision to the patient, along with their desire to be lens free for select, or most,

activities, your doctor will tell the patient, "Based on your answers, I am going to recommend that we implant the ____ IOL." Your doctor should give a brief explanation as to why they think the patient is a good candidate for the IOL they recommend and tell them that a surgical counselor will further explain their IOL options. Your doctor should also tell them that if they have any questions after visiting with the surgical counselor, they would be happy to speak with them again.

Step #4: The Vision Assessment Questionnaire is taken to the surgical counselor. The surgical counselor reviews the doctor's IOL recommendation and begins to walk the patient through the IOL CounselorTM software.

Alternative to #4: If the surgical counselor is busy with another patient, select the Patient Video and have them watch the five-minute overview video. This is accessed from the Module Selection page. This video can also be used in the exam room and waiting room to pre-educated patients about presbyopia correcting IOLs. This program is only available in English.

Step #5: Once the patient makes a decision on whether or not to follow your doctor's IOL recommendation, ask them to verify their selection on the IOL Acceptance Form. (These forms are found in Microsoft Word formats on the IOL CounselorTM CD and can be modified to fit your practice needs.)

SECTION II: SETTING UP YOUR IOL COUNSELORTM

This section will provide the surgical counselor with a page-by-page description of the features of the IOL CounselorTM software and make scripting suggestions for each page. This information is also covered in the Video Tutorial under the title, "Using the IOL CounselorTM with Patients."

SET-UP PAGE

Password to Return to this Set-Up Screen

The Set-Up page is designed to be a one-time set-up page. If you need to change your settings after you have saved them onto your hard drive, you can return to this page from the Module Selection page. However, you will have to enter the four-letter password "iolc" for IOL Counselor. This will keep curious patients from ever getting into your set-up page. You may also change this password to any word you prefer. If you forget your password, simply close the program and open it again and it will open to the Set-Up Screen and you will see your password in the password field.

First, enter the *Practice Name or Clinic Name*. If you have more than one doctor, we suggest leaving the doctor name box blank. These two fields will appear on each and every page of content to help brand the IOL CounselorTM with your practice.

Enter Fees for Payment Plan Calculator for Each Patient Type This section is not applicable outside of the US.

Available IOL Simulations

This section allows you to select which IOL simulations you want to activate on your simulator. Check www.iolcounselor.com for new IOL simulations.

Available Simulation Sceneries

There are three sceneries that are included in the IOL CounselorTM: Baseball, Supermarket, and Driving. You can select which of these scenes you want to have while counseling the patient. Check www.iolcounselor.com periodically for new sceneries that you might like to have for your geographical area or during various times of the year.

Selection Page Slide Shows/Movies

When on the Selections Page there are a number of slide shows and movies available for showing on this page. Check www.iolcounselor.com for new slide shows and movies for this section of the IOL CounselorTM.

These images were created by Eyeland Design Network. Many of them can be purchased for use in brochures, print ads, pocket folders, posters, etc., and DVDs containing these images can be purchased to play on reception room screens. Visiting www.pec-imagestock.com to see our latest offerings.

The "**How to Use the IOL Counselor**TM" tutorial video can be accessed at the bottom of the Set-Up page. Anyone unfamiliar with the IOL CounselorTM should view this program before using the IOL CounselorTM with patients.

Save and Continue

"save and continue" will record all of this information onto your hard drive, so you will not have to enter this information each time you turn on your computer or open the IOL CounselorTM software. You will then be taken to the IOL CounselorTM Module Selection page.

SECTION III: COUNSELING THE PATIENT

IOL CounselorTM MODULE SELECTION Page

There are only two options on the Module Selection page - **Patient Video** and **Patient Counselor**.

The **Patient Video** is a six-minute ENGLISH ONLY overview program on presbyopia correcting IOLs. It can be used in the exam room, reception room, or counselor's office, or can be ordered from Patient Education Concepts, Inc., in DVD or CD/Video by calling (800) 436-9126. This program is copyrighted by Patient Education Concepts and cannot be reproduced without express written permission. The program uses images from the IOL CounselorTM to explain refractive errors, IOL options, and lens replacement surgery. Showing it to your patients in advance of your counseling session will further reinforce your educational efforts.

The **Patient Counselor** image takes you to the Selections page where you will begin your counseling session with each patient.

SELECTIONS PAGE

At the bottom left of the SELECTIONS page, there is a back-to-MODULE SELECTION button that will allow you to go back to the Module Selection page if you want to show the video to the patient. You can also go back to the Module Selection page from any page in the Surgical Counselor section by clicking on the small back icon in the top right, under the practice name.

Also, at the top right, you will see a sound icon that will allow you to mute the music being played under the Selections page.

The (i) button contains copyright notices and reminders about getting updates to the IOL CounselorTM at www.iolcounselor.com.

The (x) button will exit you from the program, and you will have to open it up and start over again if you accidentally X out of the program.

First, you will need to make one of three selections:

Cataract - Medicare

Cataract - Non-Medicare

Refractive Lens Exchange

These patient categories are not relevant outside of the US but any practice using the IOL Counselor must still check one of the three boxes. Its purpose was to assign a cost in US dollars to the procedure based on the patient's insurance coverage. However, it is not possible to get to the simulations screens without checking any one of them.

Second, review your doctor's recommendation for an IOL on from the *Vision Assessment Questionnaire* and check the appropriate IOL Recommendation to advance to the next page.

Next, decide which Scenery you would like to show or start with for your session. If you have a sports-minded gentleman, you might want to select Soccer. If you have a senior lady, you might want to select Supermarket. If you have a young, active male or female, you might want to select the Driving scene. If you have downloaded a language other than English, there will be European sceneries that might be more appropriate for your patients.

All scenes have day scenes while only a few have a nighttime option.

Once you have chosen the Scenery, Patient-Type, and IOL Recommendation, you will advance to the DISCLAIMER page.

Disclaimer Page

As mentioned in the introductory paragraphs of this manual, the IOL CounselorTM is NOT a tool to assist in the informed consent process. However, you want to make it abundantly clear to each and every patient that **it is impossible to create a simulation that will show someone exactly how they will see with any IOL in any light condition**. It is very important that you read this page to them prior to moving into the actual simulation page. After reading this to a few patients, you will begin to be able to summarize it in your own words, but **don't leave out anything**. Each of the IOL types has slightly different disclaimer pages, so be sure to follow the unique text on each selection. Do Not Proceed until you have read or discussed the Disclaimer page. Click on *Continue* at the bottom right to proceed to the IOL SIMULATOR pages.

IOL Simulator Pages

As a surgical counselor using the IOL CounselorTM, you are encouraged to develop your own counseling style, using your own words based on your knowledge of the patient's needs and your doctor's desire for you to cover specific features available on the IOL Simulator pages. It is highly recommended that you and your doctor practice by role playing while using the IOL Simulator pages so that you are in agreement with how and what you are to say to your patients.

Start by selecting Supermarket scene, Medicare Patient, and Accommodating IOL recommendation.

In order to move the pointer down the Slider Bar, position the mouse cursor over the pointer, hold down the left mouse button, and slowly move the pointer to the right.

How much time you spend with each patient depends on how preconditioned they are to have one of these new IOLs. A short session might go like this:

Starting at "Normal" on the Slider Bar, use the mouse to point out zones in the scenery and tell them, "If we had Normal Vision when we were young, we could see near, intermediate, and distant objects without the need for glasses."

Slowly move the pointer to "Presbyopia" and tell them, "But as we age, usually around the ages of 40 to 45, the lens inside the eye begins to harden and lose its ability to change its focus, making it necessary to use reading glasses and eventually bifocals or trifocals to see near and intermediate zones. This condition is called 'Presbyopia."

Then slowly move the pointer to "Cataract." Notice that as you continue moving to the right, the visual symptoms of cataracts increase in severity. Stop the pointer in front of the Surgery button.

Tell your patient, "If we live long enough, most of us will develop cataracts. This occurs when the natural lens inside the eye continues to harden and becomes cloudy. Left untreated, cataracts could eventually cause blindness. So your doctor is going to remove the cloudy lens and replace it with a clear, artificial lens, called an intraocular lens or IOL."

Move the pointer past the Surgery button and stop under the words "Standard Monofocal IOL." You'll see the flash image of an IOL come over the scene, symbolizing that you are now looking through an intraocular lens.

Tell your patient, "After the cataract has been removed, you can choose to have a standard, monofocal IOL, paid for by Medicare, which usually provides good distance vision. But, you'll probably be dependent on readers or bifocal glasses for most of your near and intermediate vision."

Then begin moving the pointer under the words "Accommodating IOL" and tell them, "However, according to your Vision Assessment Questionnaire, your doctor thinks you would benefit from the Crystalens that CAN provide a full range of vision, from near to intermediate to distance." Be sure to point out the near, intermediate, and distant zones as you are speaking to them.

Then say something like, "Which IOL would you would prefer, the standard monofocal, or the premium, Crystalens?" Wait for their response. You might want to click back and forth on the Slider Bar under Monofocal, then under the Accommodating IOL, as this will take you instantly to each simulation, further emphasizing the difference between the two IOLs.

If they respond, "Does my insurance cover the multifocal lens?" Tell them, "Medicare will cover the cost of cataract surgery with the standard monofocal IOL, but there are additional physician services and diagnostic tests required for the Accommodating IOL which insurance does not cover. The additional cost is _____," and tell them the price.

If they say, "OK. That's what I want. The counseling session is over. If they say, "That's expensive!" or, "That's more than I can afford," Tell them, "Due to the advanced technology of the presbyopia correcting IOL, it does cost more than a monofocal IOL. However, many of our patients feel the additional expense for these lenses is well worth the higher quality of vision they enjoy after surgery.

"Do you have any questions about the differences between these lenses?"

"Would you prefer that we implant the presbyopia correcting IOL or the monofocal IOL?"

Before or on the day of surgery, process the CareCredit transaction on the CareCredit credit card terminal. If you need assistance, please call 1-800-839-9078.

Changing Scenes from the Simulator Page

Back on the Simulator page you will see three numbered icons on the far right.

If you have just demonstrated one of the other day scenes, and you want to demonstrate night vision, you can click on another scene to switch to the "Driving" scene which has both day and night scenes.

To change from day to night, click on the "Moon" icon on the right. Notice that when you change from day to night, the coffee cup is no longer in the scene.

Normal, Presbyopia, and Cataracts can also be demonstrated at night using the same language we suggested earlier. But, when you move the pointer under the Standard Monofocal IOL night scene, you could say, "With the standard monofocal IOL, you should experience improvement in your night vision compared to how you probably see now with cataracts. However, notice that there will still be some glare around lights and your near and intermediate vision will not be as good as your distant vision."

If you are showing the Multifocal IOL simulation, stop at the beginning of the timeline. Tell the patient, "With the multifocal IOL you will notice rings or halos around lights. Most patients report that these are more noticeable immediately after surgery, but they become less noticeable over time as the brain adapts to seeing through the multifocal lens."

Tell them to watch the car lights in the distance while you move the pointer slowly along the time line. Tell them to notice how the halos diminish over time and how they really shouldn't interfere with one's ability to see their surroundings by pointing to the pedestrians on the sidewalk, the signs, and the painted stripes on the street. Also point out how the dashboard is in focus as well.

To reinforce the concept of neuro-adaptation, you might want to click back and forth on the Slider Bar at the beginning of the timeline and then at the end of the timeline, several times.

Refractive Error Pages

If the patient asks about correcting their nearsightedness, farsightedness, or astigmatism, click on the Refractive Errors button at the bottom of the simulator. Here you have the option of telling the patient, "In addition to having a cataract, you also are a) nearsighted, b) farsighted, c) have astigmatism, or d) you are both a, or b, and have c." Or, if the Patient-Type is Refractive Lens Exchange, you would start in the same way but not mention having a cataract.

The Slider Bar in the Refractive Errors Simulator page allows you to start with a normal, Healthy eye.

Normal

Start by moving the pointer along the Slider Bar to explain how the Normal Eye works. You might say, "In a young, normal eye, light passes through the cornea, then through the clear natural lens inside the eye, and comes to a single point of focus directly on the retina. This provides a full range of clear vision from near to intermediate to distance." Then click on their refractive error type.

Nearsighted

As you click on the Slider Bar and slowly move it toward *Advanced*, you will see in the Patient View how the distance vision becomes more and more blurry. Tell them, "A nearsighted eye is too long in relation to its corneal curvature, or has a cornea that is too curved for the length of the eye. This causes light rays to come to a point in front of the retina, instead of on the retina. Nearsighted people can usually see well up close longer than normal-sighted people, but nearsighted people usually lose the ability to see close up by their late forties or early fifties."

Farsighted

As you click on the Slider Bar and slowly move it toward *Advanced*, you will see in the Patient View how the near image becomes more and more blurry. Tell them, "A farsighted eye is too short in relationship to its corneal curvature, or has a cornea that is too flat for the length of the eye. Many farsighted people see well at a distance but need reading glasses to see well up close. Young people with minor amounts of farsightedness can often see clearly both near and far until they approach the age of forty."

Astigmatism

As you click on the Slider Bar and slowly move it toward *Advanced*, you will see in the Patient View how the near image becomes more and more blurry and distorted. Tell them, "An eye with astigmatism has a cornea that is irregularly shaped, more curved in one direction than the other. This causes light images to focus at multiple points, resulting in blurry vision. Astigmatism can occur by itself, or simultaneously exist with nearsightedness and farsightedness."

Summary of Refractive Errors Page

If you use the Refractive Errors page in your counseling session and your patient has significant astigmatism, you will need to discuss how to position the surgical correction of their astigmatism. On the *IOL Simulator page*, you will have an option to select *Surgery*, and that will show PRK, LASIK, or Limbal Relaxing Incisions. Again, be sure to role play with your doctor so that you know how to address astigmatism in your session.

Surgery Animations Page

Click on the Surgery "Movie" icon in the middle. Here, there are short animations showing phacoemulsification with lens implantation, LASIK, PRK, and Limbal Relaxation Incisions.

Showing these procedures in advance of their surgery is not usually necessary unless the patient specifically asks you how the natural lens is removed, or how you are going to eliminate their astigmatism or residual refractive errors. You and your doctor should discuss which of these surgical options you might want to cover with patients and when it is appropriate to do so.

Counseling for the Aspheric Monofocal IOL

From the SELECTIONS page, select the Driving Scene, any Patient-Type, and Aspheric IOL.

Read the disclaimer for the aspheric monofocal IOL as it is different from the multifocal IOL disclaimer and covers the differences between aspheric and spherical IOLs.

Click on Continue to go to the Simulator page.

In the day scene, you will not see a stark difference between the standard monofocal lens and aspheric lens, although there is a slight improvement in contrast.

You might want to click on the Slider Bar going back and forth between the standard IOL and the aspheric IOL a couple of times to make it more detectable.

Then, click on the "Moon" icon for the night scene, and move the pointer to the standard monofocal night scene. This simulation is exactly like the standard "spherical monofocal IOL" simulation shown while demonstrating the multifocal IOLs.

But, as you slide the pointer over to the aspheric monofocal lens, you'll notice a considerable increase in contrast and the elimination of glare and halos around the lights, which is the primary benefit of having an aspheric monofocal lens versus a standard spherical lens.

Showing this demonstration to someone who may have wanted a presbyopia correcting IOL, but who was not a good candidate for one reason or the other, allows you to present them with an IOL option that represents a significant advancement in IOL technology.