Crystalens® Accommodating Posterior Chamber Intraocular Lens

BRIEF STATEMENT

Rx only.

Indications for Use: The Crystalens® is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia secondary to the removal of a cataractous lens in adult patients with and without presbyopia. The Crystalens® provides approximately one dioptr of monocular accommodation which allows for near, intermediate, and distance vision without spectacles.

Warnings: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient. Some adverse events which have been associated with the implantation of intraocular lenses are hypopyon, intraocular infection, acute corneal decompensation, and secondary surgical intervention.

Precautions: Do not resterilize; do not store over 45°C.

ATTENTION: Refer to the Physician Labeling for complete prescribing information.

This resource is intended for use by physicians and other healthcare professionals involved in patient care. It is not intended and should not be construed as medical advice, nor is it intended to replace sound clinical judgment in the delivery of healthcare services. All medical and clinical data contained or made available in this resource is intended to supplement the knowledge of physicians and other healthcare professionals involved in patient care. The absence of a warning for a given procedure, technique or suggestion contained in this resource should not be construed to indicate that such procedure, technique or suggestion is safe, appropriate or effective in any given patient.

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Patient Selection And Consideration

Indications

- Crystalens® is intended for primary implantation in the capsular bag of the eye for the visual correction of aphakia secondary to the removal of a cataractous lens in adult patients with and without presbyopia
- Crystalens provides approximately one diopter of monocular accommodation, which can offer near, intermediate, and distance vision without spectacles

The Ideal Patient

Physical Attributes

- Good ocular health
- Potential for good visual acuity (VA) in each eye
- Does the patient have corneal astigmatism?
  - Plan for treatment if over 0.75 D
  - Limbal relaxing incisions can be done during IOL implantation
  - Refractive enhancements can be done three months post-op (any necessary YAG capsulotomy should be done prior to any refractive surgery)
  - VA outcomes will be enhanced by bilateral implantation
- If you are just starting with Crystalens, please see additional patient selection criteria for initial surgeries

Psychological Attributes

- Nondemanding
- Realistic expectations
Pre-Op Suggestions

Pre-Op Measurements

- Use the IOL Master and/or manual keratometry to obtain keratometric readings before any eye drops, applanation, or corneal manipulation
- For contact lens wearers, ensure that contact lens use has been discontinued long enough to provide corneal stability
- Use the IOL Master and/or immersion ultrasonography to measure axial length
- Make sure As and Ks correlate with oldest known refraction

Pearls For Accurate Biometry

Things to consider before you start:

- Measure K readings on an untouched clear cornea (no drops, applanations, etc.)
- Take note of any dry eye or other ocular pathology that may affect the corneal surface and fixation
- For contact lens wearers, ensure that contact lens use has been discontinued long enough to provide corneal stability
  - Take two readings one week apart showing stable measurements before accepting the measurement for IOL calculations
- If the patient is pseudophakic and axial length is being verified post-operatively, ensure that the velocity is set for the IOL material

Keratometry

Manual

- Make sure the keratometer is calibrated on a regular basis
- Focus the ocular lens before taking any measurements
- Take at least three readings per eye to ensure accuracy and consistency of measurements
- Have the patient blink frequently between measurements to avoid drying the cornea
- If the patient has dry eye, artificial tears may help obtain more reliable measurements

IOL Master

- Run instrument calibration every day
- Alignment is important; make sure all six measuring points are visible and between the two auxiliary circles
- The six measuring points must be in focus
- Have the patient blink a few times and open wide before pressing the button
- If the patient has dry eye, artificial tears may help obtain more reliable measurements

Axial Length Measurement

Immersion

- Calibrate instrument each day that the instrument is in use
- Make sure your machine is set properly
  - Phakic, pseudophakic, etc.
  - Gates and gain
- Patient fixation and probe alignment are important. When all five spikes (cornea, anterior lens surface, posterior lens surface, retina, and sclera) are high and steeply rising, you are most likely on the visual axis. Posterior to the scleral spike, you should see multiple spikes that drop off in height (orbital fat).
- If the scleral spike is missing and very few small spikes are observed posterior to the retinal spike, you are most likely measuring into the optic nerve

IOL Master

- Make sure your machine is set properly
  - Phakic, pseudophakic, etc.
- The patient should fixate on the red fixation light
- You can maneuver the central focusing spot within the measurement reticule to obtain the best signal curve display
- You can defocus (in or out) if needed to improve the display
- Signal-to-noise ratio (SNR) should be above 2.0
For All Measurements

• Reproducibility and accuracy are absolute requirements
  - Keratometry: repeated measurements should be within 0.12 D in each meridian
  - Immersion: SD should be within 0.09 mm
  - IOL Master: at least 4/20 measurements must be within 0.02 mm, with good signal curve display and SNR > 2.0
• Do not hesitate to have a second examiner confirm your measurements

Putting It All Together

Keratometry

• The amount of astigmatism must correlate with the oldest known refraction
• If there is a difference of >0.50 D between OD/OS, does it correlate with the oldest known refraction?

Axial Length

• The axial length must correlate with the oldest known refraction
• If there is a difference of >0.3 mm between OD/OS, does it correlate with the oldest known refraction?

Surgical And Post-Op Pearls

Surgery Recommendations

Lens Power Calculations

• The SRK-T formula will be used for eyes with axial lengths measuring 22.01 mm or longer
  - Recommended starting A constant for the Crystalens AO™ is 119.1, Crystalens HD™ is 118.8, and Crystalens Five-O™ is 119.0
• The Holladay II formula will be used for eyes with axial lengths measuring 22.0 mm or shorter
• The Holladay II is suggested for eyes with Ks flatter than 42.00 D or steeper than 47.00 D, independent of axial length
• Manufacturer’s recommended starting ACD for Crystalens AO is 5.61, Crystalens HD is 5.43, and Crystalens Five-O is 5.55

Targeting

For the Crystalens AO and Crystalens Five-O:

• Distance eye: select the lens that predicts between plano and -0.25
• Near eye: select the lens that targets between -0.25 and -0.50

For the Crystalens HD, the optimal refractive target for each eye is plano. In those cases where the lens calculation does not result in a lens that targets plano, the following is suggested:

• Distance eye: select the lens that predicts the first plus outcome above plano
• Near eye: select the lens that predicts the first minus below plano

Accurate manifest refraction is critical — take time to refine. In choosing which eye to operate on first, select the eye with the worse cataract. If cataracts are equal, select the eye most likely to impress the patient.

Crystalens Nomogram For Short Eyes

<table>
<thead>
<tr>
<th>Axial Length</th>
<th>Formula</th>
<th>Target To Achieve</th>
</tr>
</thead>
<tbody>
<tr>
<td>21.0 mm or Less</td>
<td>Holladay II</td>
<td>+0.25, -0.50, -0.75</td>
</tr>
<tr>
<td>21.01 mm to 22.0 mm</td>
<td>Holladay II</td>
<td>PI, -0.25, -0.50</td>
</tr>
</tbody>
</table>

Surgical And Post-Op

• Create a symmetrical capsulorhexis measuring 5.5 mm to 6.0 mm
• Ensure that both plates and all four haptics are secure in the capsule; the optic should be well centered and in a posterior position
• Use one drop of atropine at the close of the case
• Post-op Day 1 uncorrected distance visual acuity (UCDVA) critical, uncorrected intermediate visual acuity (UCIVA), and uncorrected near visual acuity (UCNVA) optional. Post-op Days 7 to 14 check UCDVA, UCIVA, UCNVA, and perform testing listed on the DataLink form and submit or enter findings.
  - Measure distance corrected near VA
  - Measure binocular acuities at all ranges after the second eye has been implanted to assess visual function
  - Verify refractive findings with a cycloplegic refraction when VAs and refraction do not correlate or if near VA is not J3 or better
  - Confirm on slit examination the vault (posterior, neutral, or anterior) and centration of the Crystalens
• It is recommended to keep patients on NSAIDs until the medication is gone and Lotemax® medication for 8 to 10 weeks
Post-Op Evaluations

Things To Consider
• In the initial post-op period, the accommodative change between distance and near may be slow
• Because Crystalens patients can accommodate, you should refract them as you would a young myope — which is very different from your normal post-op routine
• Before the examination, most patients are sitting in the waiting room reading — which means they are probably accommodating
• Evaluate all distance measurements before doing intermediate and near measurements

Suggested Techniques For Post-Op Evaluations
• Remember to measure intermediate VA
• Measure the UCDVA, giving the patient time to blink and focus
• Determine the starting point for your maximum plus refraction
  - Ensure that the UCDVA and the target outcome correlate (refer to chart on page 10)
  - Auto-refractors tend to over-minus — DO NOT use this sphere as your starting point
  - K readings will indicate the approximate amount of cylinder and the axis
  - If performing retinoscopy, ensure that the patient is fixating on a letter on the chart and not on the retinoscope
  - Use this information to determine your starting point in the phoropter
• Tell the patient it might appear blurred and see how far down the chart they can read
• Isolate the line that is two lines above the lowest line that the patient can read. Slowly add plus sphere power until the line is fully blurred. It may take 1.50 D to 2.00 D of additional plus sphere to accomplish this.
• Isolate the 20/25 line. Tell the patient it will be blurred. Slowly add minus until the patient can read it. Next, isolate the 20/20 line and add minus sphere in small steps. Only give minus if the patient can read more letters. Do not use the “which is better?” technique. By relying on letters read, you are making this a more objective test.
• Refine the cylinder axis and power with the Jackson Cross Cylinder
  - Maintain spherical equivalent by adjusting 0.25 D of sphere for every 0.50 D of cylinder change
• Have the patient read the smallest line possible
• At this point, the patient has to “earn” any more minus. If they can read more letters, or if it is “definitely clearer,” they get it. If they cannot see more letters, or if it is “darker and smaller,” they DO NOT get additional minus.
• Generally, you have reached your endpoint if adding a little plus makes the image blurred, and if you add minus, it stays the same or darker. No matter how much they might like more minus, you have to stop unless it truly helps them see better. Do not hesitate to repeat fogging if you think it is necessary. It is faster and easier to do it now, rather than coming back after the next set of steps. (You can add +1.00 D sphere, change the smallest line, and slowly reduce power by 0.25 D steps to see if you have the same endpoint.)
• Measure UCIVA at 28” to 32” and then UCNVA at 16”, again giving the patient time to blink and focus

Corrected VA Assessments And Add Power
• Measure all ranges of vision (distance, intermediate, and near) as above, but through the distance correction
• With the near card at 16”, slowly add plus over the distance correction in 0.25 D steps until the patient can read J1. If the add is more than +1.50 D, you may have over-minused the sphere.

Things To Reconsider
• Do the uncorrected visions (all ranges) correlate with the refraction?
• If you think the patient may be over-minused and you cannot “undo” it, recheck the UCDVA. If the vision has decreased since the start of the examination, ask the patient to relax and refocus at a distance target.

Cycloplegic Refraction
• If your patient is not reading J3 or better through the distance correction, you must do a cycloplegic refraction to rule out subtle hyperopia/over-minus/accommodative spasm
• This is a very important step in assessing the true maximum plus refraction in an accommodating Crystalens patient
• After following the steps above, give the patient Cyclopentolate® 1%, 1 drop q5min x2. Wait at least 30 minutes (the patient may dilate before they are actually cyclopleged).
• Refine the refraction. Measure distance VA only.
Expected Outcomes

<table>
<thead>
<tr>
<th>Distance</th>
<th>Intermediate</th>
<th>Near</th>
<th>Spherical Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/40</td>
<td>20/20</td>
<td>J1</td>
<td>-0.75</td>
</tr>
<tr>
<td>20/30</td>
<td>20/20</td>
<td>J2+</td>
<td>-0.50</td>
</tr>
<tr>
<td>20/25</td>
<td>20/20</td>
<td>J2</td>
<td>-0.25</td>
</tr>
<tr>
<td>20/15</td>
<td>20/20</td>
<td>J3+</td>
<td>0.00</td>
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</table>

**SPECIFICATIONS**

**Product Specification for all Crystalens Models:**
- Optic Diameter: 5.0 mm
- Shape: Biconvex
- Material: Biosil®

<table>
<thead>
<tr>
<th>Model</th>
<th>Recommended Starting A Constant</th>
<th>Recommended Starting ACD</th>
<th>Overall Diameter</th>
<th>Diopter Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystalens AO™</td>
<td>AT50AO</td>
<td>119.1</td>
<td>5.61 mm</td>
<td>11.5 mm</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>+17 to +33 in 0.50 steps</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>+18 to +22 in 0.25 steps</td>
</tr>
<tr>
<td>Crystalens HD™</td>
<td>AT52AO</td>
<td>119.1</td>
<td>5.61 mm</td>
<td>12.0 mm</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>+10 to +16.50 in 0.50 steps</td>
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<td></td>
<td></td>
<td></td>
<td>+17 to +33 in 0.50 steps</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>+18 to +22 in 0.25 steps</td>
</tr>
<tr>
<td>Crystalens Five-O™</td>
<td>HD500</td>
<td>118.8</td>
<td>5.43 mm</td>
<td>11.5 mm</td>
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<td></td>
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<td>+17 to +33 in 0.50 steps</td>
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<td>+10 to +16.50 in 0.50 steps</td>
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<td>+17 to +27 in 0.25 steps</td>
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<td>+27 to +33 in 0.50 steps</td>
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<td>+4 to +10 in 1.0 steps</td>
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<td>+10 to +16 in 0.50 steps</td>
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<td></td>
<td></td>
<td></td>
<td>+16 to +16.75 in 0.25 steps</td>
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</tbody>
</table>

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FOR CLINICAL SUPPORT CALL: 1-888-393-6642