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**Indications for Use:**
The KAMRA® inlay is indicated for intrastromal corneal implantation to improve near vision by extending the depth of focus in the non-dominant eye of phakic, presbyopic patients between the ages of 45 and 60 years old who have cycloplegic refractive spherical equivalent of +0.50 D to -0.75 D with less than or equal to 0.75 D of refractive cylinder, who do not require glasses or contact lenses for clear distance vision, and who require near correction of +1.00 D to +2.50 D of reading add.
Setting the Standard in Presbyopia Correction

As the only presbyopia procedure utilizing small aperture optics, the KAMRA® inlay offers the long term performance solution you’ve been waiting to offer your presbyopic patients. With the KAMRA inlay you are giving your patients a:

• Safe, proven, sustainable near vision solution
• Complete uninterrupted range of vision
• Minimally invasive procedure
• Treatment that leaves the natural lens in place
• Lasting vision treatment

Made from Polyvinylidene Difluoride (PVDF)
KAMRA® SMALL APERTURE TECHNOLOGY

- Is based on principles of small aperture effect to increase the eye’s depth of focus.
- The inlay does not split light between near, intermediate, and distance focal points.
- Results provide good near vision with minimal compromise in distance vision.

Young Eye

Presbyopia

With Inlay
CORRELATING “F-STOP” TO PUPIL SIZE

• The pupil of the human eye is its aperture
• The iris is the diaphragm that serves as the aperture stop
• The entrance pupil can range from 2 mm to 8 mm depending on lighting conditions and iris response
DEPTH OF FOCUS WITHOUT CORRECTION

Subjective assessment with the AcuTarget HD™ instrument shows this eye has only 0.25D of depth of focus.
DEPTH OF FOCUS WITH THE KAMRA® INLAY

Subjective assessment with the AcuTarget HD™ instrument shows the eye with the inlay has >2.50D of depth of focus.
### PATIENT SELECTION

<table>
<thead>
<tr>
<th>Inclusion Objective Criteria</th>
<th>Inclusion Subjective Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Age: between 45 and 60 years old</td>
<td>- Dislikes reading glasses</td>
<td>- Previous corneal surgery</td>
</tr>
<tr>
<td>- Spherical Equivalent between Plano to -0.75 D</td>
<td>- Views loss of near vision as a disability</td>
<td>- Any ocular or systemic disease that is a contraindication for corneal refractive procedures:</td>
</tr>
<tr>
<td>- Astigmatism ≤ 0.75 D</td>
<td>- Cosmetic and lifestyle motivated</td>
<td>- Kerataconus</td>
</tr>
<tr>
<td>- Stable refraction for minimum of 1 year</td>
<td>- Easy going</td>
<td>- Severe dry eye</td>
</tr>
<tr>
<td>- Pachymetry &gt; 500 microns</td>
<td>- Willing to participate in recovery process</td>
<td>- Cataracts</td>
</tr>
<tr>
<td>- Mesopic pupil size ≤ 6.0 mm</td>
<td></td>
<td>- Macular degeneration</td>
</tr>
</tbody>
</table>

**Exclusion Criteria**

- Patients with unrealistic post-op expectations
- Patients with psychological conditions
OBJECTIVE PATIENT SELECTION

- Careful patient and procedure selection results in the best possible outcome for patients and practices.
- Pre-op refractions should be the primary driver for procedure selection.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Emmetropes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Type</td>
<td>Pocket Emmetropic KAMRA® (PEK)</td>
</tr>
<tr>
<td>Age</td>
<td>45-60</td>
</tr>
<tr>
<td>Spherical Equivalent</td>
<td>Plano to -0.75D</td>
</tr>
<tr>
<td>Cylinder</td>
<td>( \leq 0.75 \text{ D} )</td>
</tr>
<tr>
<td>Mesopic Pupil Size</td>
<td>( \leq 6 \text{ mm} )</td>
</tr>
<tr>
<td>Corneal Thickness</td>
<td>( &gt; 500 \text{ microns} )</td>
</tr>
<tr>
<td>*Pocket Depth</td>
<td>200-250 microns</td>
</tr>
</tbody>
</table>

* Use surgeon discretion for pocket to endothelium distance.
PRE-OP REQUIRED TESTING

PATIENT HISTORY
- Ocular
- Medical

VISION ASSESSMENT
- UCVA (distance & near)
- BCVA
- Dry Refraction
- Cycloplegic Refraction
- Eye Dominance
- Cover Test
- Lensometry

OCULAR ASSESSMENT
- OCT
- AcuTarget HD™
- Slit Lamp Exam
- Mesopic Pupil Size
- Topography
- Tonometry
- Corneal Diameter (WTW)
- Dry Eye Assessment
- Pachymetry
- Posterior Segment
ACUTARGET HD™ INSTRUMENT

Centration Planning

- Proper inlay placement is an important factor in achieving good outcomes and effectiveness.

- Inlay should be placed within 300 microns from desired position for best results.

- If the Purkinje vs. Pupil Cord Length is > 300 microns, the inlay should be placed half way between the center of the pupil and the 1st Purkinje image.
Objective Scatter Index (OSI Assessment)

- Subjective assessment of the patient’s lens opacity does not always detect early lens changes.

- Objective assessment is utilized by the AcuTarget HD™ instrument for detecting and quantifying all lens changes, even early changes, which is highly correlated with the Lens Opacities Classification System III (LOCS III).
Tear Film Assessment

- Evaluates tear film quality
- OSI evolution with time identifies patients with dry eye
- Reinforces the need for ocular surface management to patients
KAMRA® INLAY PROCEDURES
POCKET EMETROPIC KAMRA (PEK)

Pocket Emmetropic Kamra (PEK)

200-250 µm

Epithelium

Pocket

Endothelium
DESCRIPTION:
A pocket is created in the stroma at a depth of 200-250 μm. The inlay is then inserted in the pocket.

SUITABLE FOR:
Emmetropic Presbyopes
POST-OPERATIVE MANAGEMENT

Happy patients are a result of:
- Appropriate patient selection
  - Psychology/expectations, dry eye management, strong eye dominance
- Successful surgical procedure
  - Optimized femtosecond laser settings
  - Achieve refractive target
  - Centration
- Stable post-operative acuity
- Satisfied patients make referrals

It is important to understand the patients recovery process:
- Understand how the inlay is performing in their daily activities, i.e.: Can they read their watch, newspaper or computer?
- Listen and provide reassurance to manage the patient’s expectations during post-op healing

Post-operatively patients may have a disrupted tear film, we recommend instilling a preservative-free artificial tear a few minutes prior to testing vision:
- Monocular and binocular acuity
- Distance, intermediate (80cm) and near (40cm), under good lighting conditions
- Refraction

Slit Lamp Evaluation:
- Corneal Surface: TBUT, NaFl staining, clarity
- Inlay Centration
- IOP Assessment

Additional Tests:
- Corneal Topography
POST-OP EXAM

• Minimum follow-up:
  - 1 day
  - 1 week
  - 1, 3, 6 months
  - 1 year
• Follow post-op management recommendations
• Evaluate visual pathway to access clarity of media from front of cornea to back of eye. The Objective Scatter Index (OSI) helps quantify quality of vision based on intraocular media changes (see figure below)
• Patients should be **seen more frequently** if abnormal post-op findings are observed

EVALUATING POST–OP CENTRATION

The only proven objective method for assessing the KAMRA® inlay centration post-operatively

- Identifies the inlay position relative to 1st Purkinje *(see figure above)*
- Accurate assessment of centration helps correlate post-op results and symptoms if a large decentration is present
<table>
<thead>
<tr>
<th>Testing</th>
<th>1 Day</th>
<th>1 Wk</th>
<th>1 Mo</th>
<th>3 Mo</th>
<th>6 Mo</th>
<th>12 Mo</th>
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</thead>
<tbody>
<tr>
<td><strong>Uncorrected VA</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Distance at 6 m/20 ft</td>
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<td></td>
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<tr>
<td>Intermediate at 80 cm/32 in</td>
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<tr>
<td>Near at 40 cm/16 in</td>
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<tr>
<td><strong>Distance-Corrected VA (No Add)</strong></td>
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<tr>
<td>Distance at 6 m/20 ft</td>
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<tr>
<td>Intermediate at 80 cm/32 in</td>
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<td></td>
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<tr>
<td>Near at 40 cm/16 in</td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Distance-Corrected VA (With Minimum Add)</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Near at 40 cm/16 in</td>
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<td><strong>Midpoint Refraction</strong></td>
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</tr>
<tr>
<td><strong>Slit Lamp Examination</strong></td>
<td></td>
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<tr>
<td><strong>Dry Eye Evaluation</strong></td>
<td></td>
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<tr>
<td><strong>Intraocular Pressure</strong></td>
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<td><strong>Computerized Corneal Topography</strong></td>
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</tr>
<tr>
<td><strong>AcuTarget HD™ Instrument</strong></td>
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</tr>
</tbody>
</table>

- Green indicates recommended tests
NEAR VISION CHART

- Attached string for consistent test distance (40 cm/ 16 in)
- 3 rows of 'small' letters to reduce memorization
- Use a bright overhead or over-the-shoulder light
- Patient should be shown improvement from pre-op to post-op in order to demonstrate effectiveness of the KAMRA® inlay starting at 1-month post-op
SUGGESTED TECHNIQUES FOR POST-OP REFRACTIONS

Due to the small aperture design, refractions can be more challenging in the implanted eye.

- The refraction end points are usually softer.
- The patient will tolerate a larger range of introduced lenses without experiencing blur.
- A “mid-point” refraction will provide the most accurate result. Alternatively a “red/green” balance test can be used.

CAUTION: Auto-refraction over a KAMRA® inlay is not recommended as it will bias results hyperopically.
REFRACTION TECHNIQUE
Performing a Mid-Point Refraction

**Step 1:** Perform a normal manifest refraction, then instruct the patient to fixate and maintain clarity on a distance optotype 2 lines above best corrected vision.

**Step 2:** Add plus lenses until first blur, record their endpoint.

**Step 3:** Starting from the baseline manifest refraction, now add minus lenses until first blur, record endpoint.

**Step 4:** Calculate the mid-point refraction using the following equation:

\[
\frac{([\text{Endpoint plus blur}] + [\text{Endpoint minus blur}])}{2} = \text{(rounded to nearest max plus 0.25 D)}
\]

**Step 5:** Add figure from Step 4 to the spherical component of the manifest refraction from Step 1; this represents the calculated mid-point.

**Midpoint Refraction: Example**

**Step 1:** Initial manifest Rx: +1.00 – 0.75 X 090

**Step 2:** Plus lenses to blur: +0.50 D (2 lenses)

**Step 3:** Minus lenses to blur: -1.75 D (7 lenses)

**Step 4:** \[
\frac{(+0.50 D) + (-1.75 D)}{2} = -0.62 D \text{ (Rounded to -0.50 D)}
\]

**Step 5:** -0.50 D + 1.00 D = +0.50 D

Final midpoint refraction: +0.50 -0.75 X 090
REFRACTION TECHNIQUE

Alternate Refraction Method
Red/Green Balance Test

To help you find the mid-point refraction the Red/Green balance test may alternatively be utilized.

1. Complete the initial manifest refraction and dim the room illumination completely.

2. Select the projector’s Red/Green filter with the appropriate target. This can be the 20/40 line or 2 lines above best corrected vision.

3. Have the patient compare the letters in the red/green sides and state which letters appear sharper, clearer or better focused or if both sides appear equally clear. (DO NOT ask if the letters are “better”, “darker” or “brighter”)

NOTE: If the patient is R/G colorblind this test may still be utilized because it is based on the principles of chromatic aberration and not color discrimination. The patient can still make a comparison. They should be asked to compare the “left” side with the “right” side rather than red vs. green.

• **RED IS CLEARER**: Place an additional 0.25 D of MINUS spherical power. Continue this until the patient reports equal clarity between sides or until the “green” side appears clearer.

• **GREEN IS CLEARER**: Place an additional 0.25 D of PLUS spherical power. Continue this until the patient reports equal clarity between sides or until the “red” side appears clearer.

• **MID-POINT REFRACTION**: The letters on both red and green sides appear equally clear.

• Remove the Red/Green filter and recheck BVA
## KAMRA® POST-OP STEROID REGIMEN

<table>
<thead>
<tr>
<th>1st Week</th>
<th>1% Prednisolone acetate QID</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd – 4th Week</td>
<td>Fluorometholone/FML QID</td>
</tr>
<tr>
<td></td>
<td>(or equivalent)</td>
</tr>
<tr>
<td>2nd Month</td>
<td>Fluorometholone/FML TID</td>
</tr>
<tr>
<td></td>
<td>(or equivalent)</td>
</tr>
<tr>
<td>3rd Month</td>
<td>Fluorometholone/FML BID</td>
</tr>
<tr>
<td></td>
<td>(or equivalent)</td>
</tr>
</tbody>
</table>

- Verify patient’s current drop regimen.
- Maintaining a proper post-op regimen optimizes the patient outcome and long term refractive stability.
- Evaluate the patient at 3 months and if appropriate discontinue steroid therapy.
- Monitor the IOP for significant increase, add an IOP lowering medication as needed.
OCULAR SURFACE MANAGEMENT

Preservative Free Artificial Tears
- Hourly for 7 days
- Tapering to q2h for 7 days
- At least QID thereafter

Punctal Plugs
- Strongly consider permanent inferior plugs

Topical cyclosporine-A (Restasis®)
- Strongly consider BID for 2 months (if available)

Additional Therapies
- Omega-3 fatty acids

Other Dry Eye Facts
- Fluctuations in vision and myopic shifts are typically a result of dry eye.
- Proactive careful management of the ocular surface will boost patient satisfaction.
- The AcuTarget HD™ Instrument can help demonstrate the effects of dry eye on visual quality and identify if patient compliance is an issue.

Instill fluorescein to assess for:
- SPK
- Dryness
- Integrity of tear film
- Breaches in the anterior corneal layers
SLIT LAMP EXAM

Inspect inlay and cornea closely for:
- Areas of irregularity or damage
- Epithelial ingrowth
- Stromal haze
- Side-cut misalignment or epithelial defects
- Stromal inflammation (DLK)- refer back to surgeon
- Striae-refer back to surgeon

- Use narrow slit beam on mid and high magnification
- Assess thickness across entire inlay
TOPOGRAPHY

Pocket Procedure:  
Post-Op Topography Analysis

• The best method to monitor the surface architecture of the cornea is with a Placido disc based topographer. This offers good analysis of the central aspects of the anterior cornea and the surface quality.

• Post-operatively there is normally very little alteration to the corneal topography.
TOPOGRAPHY

Topography
Map Settings

• Consideration should be given to axial map findings as other maps can over emphasize the presence of central corneal changes.
• Set the axial map scale to 0.50 D steps

Axial Map

Instantaneous Map

Image courtesy of Dr. Francesco Carones
TOPOGRAPHY CHANGES

Blue Ring

- The presence of a blue ring is evidence of tear film irregularity.

- Disruption in tear film quality over the inlay may result in:
  - Flattening over the inlay (blue ring on topography)
  - Steepening centrally (green centrally)
  - A myopic shift

- Treat ocular surface / dry eye management

*Image courtesy of Dr. Francesco Carones*
**TOPOGRAPHY CHANGES**

Red Ring

- It is normal to see a red ring on topography and by itself should not require therapy.
- Elevation over the inlay (red ring) **may** be influenced by:
  - Time since surgery
    - Corneas can be steeper during the initial post-op period
  - If a red ring is noted, perform a complete ocular assessment to rule out a possible wound healing response.

---

**CASE 1:**
Depth: 187 micron
UNVA: 20/20

**CASE 2:**
Depth: 179 micron
UNVA: 20/25

**CASE 3:**
Depth: 171 micron
UNVA: 20/20

*Image courtesy of Dr. Francesco Carones*
RECENTRATION DECISION TREE

Assess the following to determine if a recentration is required to improve vision:

EVALUATE FOR SYMPTOMS
Decreased Vision
Vision Not Improving
Shadow in Vision
Near Vision Inadequate

EVALUATE OBJECTIVE CLINICAL FINDINGS

Does day 1 AcuTarget HD™ instrument show the inlay placement within 450 μm of intended location?

† Assess the following to determine if a recentration is required to improve vision:

YES

Is UCNVA, UCDVA, or BCDVA below expected levels and not improving over 3 months post-op?*

No

Recentration not required.
Monitor.

YES

Is MRSE between Plano and -1.00 D?

No

Recentration not required.
Consider refractive enhancement.

YES

Is the ocular surface clear and free of SPK and other signs of dry eyes?

No

Recentration probably not required.
Implement aggressive dry eye therapy and recheck in 4 weeks.

YES

Is the placido disk topography normal? (Orbscan, Pentacam not valid)

No

Recentration probably not required.
See Wound Healing Response decision tree.

YES

Were the proper femtosecond laser settings utilized and does the stromal interface appear clear?

No

Recentration probably not required.
Consider AcuTarget HD™ instrument or 90 D lens to assess ocular scatter. Follow patient monthly.

YES

Is the patient's lens free of cataracts?

No

Recentration not required.
Consider cataract surgery.

YES

Is the retina normal and free of pathology?

No

Recentration not required.
Refer to retina specialist.

YES

Does the AcuTarget HD™ post-op measurement show the inlay to be placed within 300 microns of the intended location?

No

RECENTRATION REQUIRED.
Perform AcuTarget HD™ assessment and recenter inlay. Have backup inlay if replacement is necessary.

NO

YES

Recentration not required.
Follow patient or consider explant.
RECENTRATION DECISION TREE

• If the patient’s vision is good through the first month and then deteriorates, decentration should be ruled out as a possible etiology.

• If vision improves to expected level over the first few months and then deteriorates, decentration is not the cause.

• If BCDVA is below expected, a hard CL over-refraction can rule out surface irregularity as a causing factor.

• To rule out forward light scatter in the visual pathway causing decrease acuity, perform one of the following:
  o AcuTarget HD™ OSI Assessment
  o Evaluate ocular surface quality and for crystalline lens media opacities

• If the patient’s pre-op vision was good and the post-op vision slowly deteriorates, consider increasing lens opacity as the cause of vision degradation.

• Similarly, if the vision was good in the early post-op period and then deteriorates. Consider the results from one/all the tests below to support the diagnosis of a progressive cataract as the cause:
  o Hard CL over-refraction provides no improvement
  o The OSI is greater than 1.0
MANAGE A WOUND HEALING RESPONSE

EVALUATE SYMPTOMS*
- Reduction in UCNVA Gain
- Blurry/Fluctuating Vision
- Dry Eye

EVALUATE SIGNS*
- Topographic Changes (elevated ring)
- Slit Lamp Findings (nebulous haze over inlay)

GRADE THE REFRACTIVE CHANGE

MILD
- Rx Change ≥ 0.50D and < 1.00D
- Minimal Signs/Symptoms
- Intervention: Ocular Surface Management
  Follow

MODERATE
- Rx Change ≥ 0.50D and < 1.00D
- Moderate Signs/Symptoms
- Intervention: Ocular Surface Management
  Reinstates Post-Op Steroids
  Follow

SIGNIFICANT
- Rx Change ≥ 1.00D
- Significant Signs/Symptoms
- Intervention: Aggressive Ocular Service Management
  Reinstates Post-Op Steroids
  Follow

RESOLVED?

YES
- No Rebound
- Follow for Stability

NO
- Without Symptoms
- But Rebounds
- Considers Explant

Symptoms and signs aid in the evaluation, but are not always present. Use refraction as the main assessment.
**MANAGE A WOUND HEALING RESPONSE**

- When a wound healing response is first diagnosed, the patient should be started on a course of steroids and dry eye therapy (See Decision Tree on opposite page).

- Refer back to surgeon
AcuFocus® is aware of reports of some cases involving use of ophthalmic laser applications in eyes containing KAMRA® inlays. Therefore we recommend the following:

**CAUTION RECOMMENDED**

**Nd:YAG Laser:** This produces highly collimated laser energy that can be focused through the center of the KAMRA® inlay and focused on the posterior capsule.

- Like an IOL, care must be taken to ensure the YAG laser beam does not cause focal damage to the inlay
- Ensure the beam is well centered within the inlay center aperture
LASER USE AFTER INLAY IMPLANTATION

NOT RECOMMENDED

Femtosecond Laser Flap Creation Over an Inlay:

- A femtosecond laser created flap is **NOT recommended** with the KAMRA® inlay in place.

- If LASIK in an inlay-implanted eye is indicated, **remove the inlay first**, then perform the LASIK procedure.

Retinal Laser Photocoagulation:

- As a result of a reported case, use of retinal laser photocoagulation (RLP) or any posterior application of unfocused laser energy, AcuFocus **recommends removal of the inlay** prior to any unfocused laser photocoagulation of the retina or vitreous.

- This avoids:
  - potential thermal damage to the inlay
  - possible secondary thermal damage to the cornea

Laser Glaucoma Procedures:

- While no issues have been reported, removal of the inlay prior to any laser-based glaucoma therapy is recommended.

For complete information please refer to the Physician Brochure.

1Corneal heat scar caused by photodynamic therapy performed through an implanted corneal inlay. Mariko Mita, MD, PhD, Tomomi Kanamori, BS, Minoru Tomita, MD, PhD. J Cataract Refract Surg 2013; 39:1768-1773
If you have any questions or challenging cases, please contact your local AcuFocus representative.

Customer Service: 949-748-4535