Table 1. Investigational Model vs. Historical Model Posterior Chamber Intraocular Lens Overall Visual Acuity (% of at least 20/40) One Year

<table>
<thead>
<tr>
<th>Age Category</th>
<th>Overall Rate</th>
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<th>Overall Rate</th>
<th>Overall Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>60-69</td>
<td>793/822</td>
<td>96.5%</td>
<td>41/41</td>
<td>100%</td>
</tr>
<tr>
<td>70-79</td>
<td>1338/1372</td>
<td>97.5%</td>
<td>71/72</td>
<td>98.6%</td>
</tr>
<tr>
<td>80</td>
<td>601/634</td>
<td>94.8%</td>
<td>17/17</td>
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</tr>
</tbody>
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Table 2. Investigational Model vs. Historical Model Overall Visual Acuity (% of at least 20/40) One Year

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</tr>
</tbody>
</table>

Table 3. Surgical Reintervention Table

<table>
<thead>
<tr>
<th>Time Interval</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2 days</td>
<td>C-</td>
</tr>
<tr>
<td>1-2 months</td>
<td>C-</td>
</tr>
<tr>
<td>4-6 months</td>
<td>C-</td>
</tr>
</tbody>
</table>

Table 4. Nd-YAG Use and Rate

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nd-YAG</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

Table 5. Notes

Notes:
- Edema and cumulative pupillary block. The C-filx lenses include (in order of frequency): Cumulative Macular Edema 2.3%, Persistent Iritis 0.3%, Hyphema 2.2%, Posterior Chamber Intraocular Lens (PICCL) 0.3%, and IOL implantation. The neodymium:yttrium-aluminum-garnet (Nd-YAG) rates for the C-filx lenses include (in order of frequency): Lumina 0.9%, Prokall 1.4%, and Prokall 1.8%
- *Presumed Adverse Event (AE) for the investigational model is defined as an adverse event that is related to the condition being treated and not related to the investigational model

Table 6. Investigational Model vs. Historical Model Posterior Chamber Intraocular Lens Specific Cumulative and Persistent Adverse Events One Year

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Investigational Model</th>
<th>Historical Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative Macular Edema</td>
<td>124/583 (2.1%)</td>
<td>5/301 (1.7%)</td>
</tr>
<tr>
<td>Persistent Iritis</td>
<td>11/383 (2.9%)</td>
<td>0/301 (0.0%)</td>
</tr>
<tr>
<td>Hyphema</td>
<td>91/383 (2.4%)</td>
<td>2/301 (0.7%)</td>
</tr>
<tr>
<td>Posterior Chamber Intraocular Lens (PICCL)</td>
<td>1/383 (0.3%)</td>
<td>0/301 (0.0%)</td>
</tr>
</tbody>
</table>
| Other potential complications of cataract or implant surgery include, but are not limited to the following: glaucoma, retinal detachment, cataract, corneal injury, cataract extraction, IOL implantation, Nd-YAG, topical corticosteroids, topical cycloplegics, lower eyelid skin, cysts, conjunctival blepharitis, corneal injury, cataract, and IOL implantation. The complications experienced during the clinical trial of the C-filx lenses include (in order of frequency): Lumina 0.9%, Prokall 1.4%, and Prokall 1.8%
- *Presumed Adverse Event (AE) for the investigational model is defined as an adverse event that is related to the condition being treated and not related to the investigational model

Table 7. Notes

Notes:
- Edema and cumulative pupillary block. The C-filx lenses include (in order of frequency): Cumulative Macular Edema 2.3%, Persistent Iritis 0.3%, Hyphema 2.2%, Posterior Chamber Intraocular Lens (PICCL) 0.3%, and IOL implantation. The neodymium:yttrium-aluminum-garnet (Nd-YAG) rates for the C-filx lenses include (in order of frequency): Lumina 0.9%, Prokall 1.4%, and Prokall 1.8%
- *Presumed Adverse Event (AE) for the investigational model is defined as an adverse event that is related to the condition being treated and not related to the investigational model

Table 8. Notes

Notes:
- Edema and cumulative pupillary block. The C-filx lenses include (in order of frequency): Cumulative Macular Edema 2.3%, Persistent Iritis 0.3%, Hyphema 2.2%, Posterior Chamber Intraocular Lens (PICCL) 0.3%, and IOL implantation. The neodymium:yttrium-aluminum-garnet (Nd-YAG) rates for the C-filx lenses include (in order of frequency): Lumina 0.9%, Prokall 1.4%, and Prokall 1.8%
- *Presumed Adverse Event (AE) for the investigational model is defined as an adverse event that is related to the condition being treated and not related to the investigational model

Table 9. Notes

Notes:
- Edema and cumulative pupillary block. The C-filx lenses include (in order of frequency): Cumulative Macular Edema 2.3%, Persistent Iritis 0.3%, Hyphema 2.2%, Posterior Chamber Intraocular Lens (PICCL) 0.3%, and IOL implantation. The neodymium:yttrium-aluminum-garnet (Nd-YAG) rates for the C-filx lenses include (in order of frequency): Lumina 0.9%, Prokall 1.4%, and Prokall 1.8%
- *Presumed Adverse Event (AE) for the investigational model is defined as an adverse event that is related to the condition being treated and not related to the investigational model
Device Description
Rayner 200E EMV IOLs are single-piece ultraviolet-absorbing acrylic hydrophilic intraocular lenses (IOLs) designed for use with a continuous curvilinear capsulectomy (CCC) or an anterior continuous curvilinear capsulorhexis just covering 360° of the anterior capsule. The Rayner EMV IOLs have a 17.0 mm limbus reference size (3.0 mm optic) in a circular ridge encircling the periphery of both the anterior and posterior surfaces of the optic. The Rayner in- and out-of-the-bag clear zone predictability is >90% within ±0.5 D.

Preloaded hydrophilic acrylic IOL injection system

Figure 1

1.  Microphthalmia
2.  Recurrent ocular disease (e.g. uveitis, significant vitreous prolapse or loss)
3.  Children under the age of 21 years
4.  Corneal decompensation or corneal endothelial cell insufficiency
5.  Persons who are pregnant or nursing
6.  Do not soak or rinse the intraocular lens with any solution other than sterile sterile water
7.  Severe Aniseikonia
8.  Iris atrophy
9.  Severe anterior capsular opacification
10.  Any condition that may compromise the IOL stability
11.  Press the plunger in a slow and controlled manner. If excessive resistance is felt when the IOL exits the nozzle. Discard the injector after use.
12.  Only the sterile package should be disposed of. The IOL and needles should not be discarded with other general waste.
13.  The anterior continuous curvilinear capsulorrhexis should be 360° and 5.0 to 6.0 mm in diameter.
14.  A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is uncertain and will require a secondary procedure.
15.  Circumstances that would result in failure of the intraocular lens implantation, such as a significant cataract following trauma or developmental defect in which appropriate support of the IOL is uncertain and will require a secondary procedure.

Contraindications

FOR PATIENTS

- If the patient is allergic to any of the ingredients used in the IOL.

- If there are any pre-existing diseases or conditions that may affect the patient postoperatively.

- If the patient has a history of intraocular surgery or has had any other type of eye surgery.

- If the patient is not satisfied with the results of previous eye surgery.

- If the patient is not willing to follow the postoperative medication regimen.

- If the patient is not willing to follow the postoperative follow-up visits.

- If the patient is not willing to follow the postoperative activities and restrictions.

- If the patient is not willing to follow the postoperative instructions.

- If the patient is not willing to follow the postoperative care.

- If the patient is not willing to follow the postoperative lifestyle changes.

- If the patient is not willing to follow the postoperative dietary restrictions.

- If the patient is not willing to follow the postoperative smoking cessation program.

- If the patient is not willing to follow the postoperative sleep position guidelines.

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