RayOne
ASPHERIC

The world's smallest incision fully preloaded IOL
Talking to surgeons indicates that they are looking for an injector that can deliver an IOL consistently, with expert control, through a micro incision with minimal wound stretch.

The dilemma? The preloaded IOL systems available to date have sought to meet these requirements by enhancing one element, be it the injector or lens. However, this means that a trade-off has to be made, usually between the ease of use or surgical outcomes.

At Rayner, we believe that the only way to create a true, fully preloaded micro incision cataract surgery (MICS) injection system that works consistently without compromise, is to design the system as one - both lens and injector. This was the inspiration behind RayOne.

When creating RayOne, we developed our MICS lens and unique patented Lock & Roll technology as part of the same design process; this combination has resulted in the smallest fully preloaded injector available (1.65 mm nozzle).

Our RayOne MICS lens is an enhanced version of the tried-and-tested C-flex platform, now in a 6 mm optic design.

We have retained the material and design benefits of our original lens, without compromising on proven stability or optical performance.
About Rayner

When Sir Harold Ridley designed the world’s first IOL in 1949, he chose Rayner to manufacture this ground-breaking invention. Rayner has remained at the forefront of innovation for nearly 70 years, focused on providing you and your patients with the best IOLs – always driven by science to improve patient outcomes and safety.

Rayner is the only manufacturer of IOLs in the UK, with its state of the art manufacturing plant and global headquarters on the south coast of England.

In 2017, Rayner strengthened its commitment to the USA with a dedicated subsidiary, Rayner Surgical Inc. - enabling Rayner to provide you with the highest possible levels of support and care.

The history of Rayner

Rayner is founded Harold Ridley and Rayner manufacture the first IOL Choyce MkI introduced Binkhorst Four-Loop lens designed First FDA approved lens C-flex spherical monofocal launches in the USA RaySert small incision IOL injector system introduced C-flex Aspheric 970C launches in the USA RaySert PLUS launches in the USA Rayner Surgical Inc. office opens in New York RayOne launches in the USA
RayOne with patented Lock & Roll technology for a smoother, more consistent rolling and delivery of the lens via micro incision

RayOne enhanced 6 mm optic

Available as an aberration-neutral aspheric lens

Based on proven haptic technology for excellent stability\(^1,2\)

Available as an aberration-neutral aspheric lens

Amon-Apple enhanced square edge for minimal PCO 1.7% at 24 months\(^7\)

Zero glistenings\(^8\)

A large fully preloaded power range is available

- One solution for all your patients
- Aspheric: +8.0 to 34.0 D

Reliable optical outcomes and a low rate of post-operative complications

Rayner’s anti-vaulting haptic technology provides excellent fixation in the capsular bag:\(^1\):

- **Superb centration** - Maximum offset of only 0.08 mm 3 to 6 months after surgery\(^2\)
- **Excellent rotational and torsional stability** - 2.3\(^\circ\) mean IOL rotation 3 to 6 months after surgery\(^2\)

Stability of RayOne IOLs

**STAGE 1**
Outer haptics begin to take up the compression forces of post-operative capsule contraction

**STAGE 2**
Outer haptics engage the inner haptics

**STAGE 3**
Haptic tips gently meet the IOL optic and are effectively locked into position
RayOne easy to use injector

Sub 2.2 mm incision

1.65 mm RayOne nozzle for sub 2.2 mm incision
- Smallest fully preloaded injector nozzle
  i. Ease of insertion
  ii. Enables true micro incision
- Parallel sided for minimal stretch
  i. Sub 2.2 mm delivery
  ii. Maintains incision architecture

Ergonomic design for ease of handling

True 2-step system

- Simple and intuitive
  i. Minimal learning curve
  ii. Minimizes error
- Increase efficiencies
  i. Designed for repeatability
  ii. Reduces operating time
- Step 1: Insert OVD into cartridge via port
- Step 2: Lock cartridge ready for implantation

Single handed plunger with minimal force required

Unique patented Lock & Roll technology for consistent delivery

- Rolls the lens to under half its size before injection
  i. Consistent, smoother delivery
  ii. Reduces insertion forces
- Fully enclosed cartridge with no lens handling
  i. Reduces the risk of lens damage
  ii. Minimizes chance of contamination

References:
When considering an intraocular lens, what’s important to you?

Aberration-neutral technology for optimal visual quality and functional visual acuity in all light conditions

RayOne Aspheric is designed with an aspheric anterior surface that creates no spherical aberration.

Studies have demonstrated that aberration-neutral technology:
- Offers improved contrast sensitivity compared with spherical IOLs
- Provides better low light level visual acuity than spherical IOLs
- Can offer more depth of field than aberration-negative IOLs by retention of the patient’s natural level of corneal spherical aberration
- Are less susceptible to the effects of decentration than aberration-negative IOLs
- Twice as many patients preferred the aberration-neutral IOL than aberration-negative
- Three times fewer reports of visual disturbances with the aberration-neutral IOL than aberration-negative

Reducing dysphotopsia by design
- Rayner’s Enhanced Square Edge Technology shows no general increase in glare from previous models without a square edge
- Low refractive index (1.46)

360° Optimised Barrier to reduce PCO
- Rayner’s 360° Amon-Apple Enhanced Square Edge creates an optimum barrier to reduce epithelial cell migration including at the haptic-optic junction. Extremely low Nd:YAG capsulotomy rates, comparable with hydrophobic acrylic lenses with square-edge optics.

<table>
<thead>
<tr>
<th>ND: YAG CAPSULOTOMY RATES</th>
<th>MEAN TIME TO ND: YAG CAPSULOTOMY</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 12 months</td>
<td>0.6%</td>
</tr>
<tr>
<td></td>
<td>9.3 ± 5.5 mths (range 2.6 - 22.7 mths)</td>
</tr>
<tr>
<td>At 24 months</td>
<td>1.7%</td>
</tr>
<tr>
<td></td>
<td>Follow-up period: 5.3 - 29 mths</td>
</tr>
</tbody>
</table>

Vacuole free material for a glistening free IOL
- Single piece IOL created from a homogeneous material free of microvacuoles
- Compressible material for delivery through a micro incision
- Excellent handling characteristics with controlled unfolding within the capsular bag
- Low silicone oil adherence
- Excellent uveal biocompatibility
RayOne™ received the maximum score for 'ease of use' for all delivery steps:

- Lock & Roll™ technology
  - Rolls the lens to under half its size before injection for consistent and smooth delivery
  - Fully enclosed cartridge with no lens handling means low risk of lens damage and contamination

- Easy to use, two step system
  - Simple design minimizes the learning curve and chance of errors
  - Efficient system reduces your operating time

- 1.65 mm nozzle
  - Smallest fully preloaded injector nozzle available
  - Sub 2.2 mm delivery for low risk of SIA

- A large fully preloaded power range is available
  - RayOne™ Aspheric +8.0 to 34.0 D
  - One system for all your patients

In a comparative study of six market-leading preloaded delivery systems\textsuperscript{15}

1. RayOne™ received the maximum score for 'ease of use' for all delivery steps:

2. RayOne was the least time consuming system for delivering the IOL
3. RayOne showed less injector tip damage post-insertion than 50% of the tested delivery systems
4. RayOne showed minimal wound stretch compared to other tested delivery systems when through a 2.2 mm incision
RayOne Aspheric Intraocular Lenses (IOLs)

The IOL preloaded within the Rayner RayOne injection system is a Rayner 600C Aspheric. The Rayner 600C Aspheric has optical and material equivalence to the Rayner C-flex 570C and 970C IOLs.

The combined IOL and injection system is referred to as RayOne Aspheric (RAO600C).

**INDICATIONS:** The Rayner 600C intraocular lens is indicated for primary implantation for the visual correction of aphakia in adults in whom a cataractous lens has been removed by phacoemulsification. The lens is intended to be placed in the capsular bag.

**CONTRAINDICATIONS:** Apart from non-specific contraindications related to any form of ocular surgery, the following specific contraindications must be respected:
1. Microphthalmia
2. Active ocular disease (e.g. chronic severe uveitis, proliferative diabetic retinopathy, chronic glaucoma not responsive to medication)
3. Children under the age of 21 years
4. Corneal decompensation or corneal endothelial cell insufficiency
5. Persons who are pregnant or nursing

**WARNINGS:** A risk/benefit ratio must be assessed before confirming a patient as a candidate for the Rayner 600C IOL implantation, if they are suffering from any of the following conditions:
1. Recurrent ocular disease (e.g. uveitis, diabetic retinopathy, glaucoma, corneal decompensation)
2. Previous ocular surgery
3. Non-age-related cataract
4. Vitreous loss
5. Iris atrophy
6. Severe Aniseikonia
7. Ocular Hemorrhage
8. Macular degeneration
9. Zonular dehiscence
10. Ruptured posterior capsule
11. Patients in whom the intraocular lens may affect the ability to observe, diagnose, or treat posterior segment diseases.
12. Surgical difficulties at the time of cataract extraction which might increase the potential for complications (e.g. persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss)
13. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
14. Circumstances that would result in damage to the endothelium during implantation.
15. Suspected microbial infection.
16. Children under the age of 2 years are not suitable candidates for intraocular lenses.

Since the Rayner 570C C-flex® IOL clinical study was conducted with lens implantations into the capsular bag only, there is insufficient data to demonstrate the safety and efficacy for ciliary sulcus placement of the 570C or 600C IOLs.

**ATTENTION:** Reference the Instructions for Use labeling for complete listing of indications and precautions.

**CAUTION:** Federal U.S law restricts this device to the sale by, or on the order of a physician.

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Discover why RayOne is in a class of its own visit rayner.com/USA

Regulatory restrictions may apply in certain markets.
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### RayOne Aspheric Technical Information

<table>
<thead>
<tr>
<th>Model Name:</th>
<th>RayOne Aspheric</th>
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<tbody>
<tr>
<td>Model Number:</td>
<td>RAO600C</td>
</tr>
<tr>
<td>Power Range:</td>
<td>+8.0 to +29.5 D (0.5 D increments) +30.0 to +34.0 D (1.0 D increments)</td>
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#### Delivery System

<table>
<thead>
<tr>
<th>Injector Type:</th>
<th>Single use, fully preloaded IOL injection system</th>
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<tbody>
<tr>
<td>Incision Size:</td>
<td>1.65 mm nozzle for sub 2.2 mm incision</td>
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<tr>
<td>Bevel Angle:</td>
<td>45°</td>
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<tr>
<td>Lens Delivery:</td>
<td>Single handed plunger</td>
</tr>
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#### Monofocal IOL

<table>
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<tr>
<th>Material:</th>
<th>Single piece Rayacryl hydrophilic acrylic</th>
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<tbody>
<tr>
<td>Water Content:</td>
<td>26% in equilibrium</td>
</tr>
<tr>
<td>UV Protection:</td>
<td>Benzophenone UV absorbing agent</td>
</tr>
<tr>
<td>UV Light Transmission:</td>
<td>UV 10% cut-off is 380 nm</td>
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<tr>
<td>Refractive Index:</td>
<td>1.46</td>
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<tr>
<td>ABBE:</td>
<td>56</td>
</tr>
<tr>
<td>Overall Diameter:</td>
<td>12.50 mm</td>
</tr>
<tr>
<td>Optic Diameter:</td>
<td>6.00 mm</td>
</tr>
<tr>
<td>Optic Shape:</td>
<td>Biconvex</td>
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<tr>
<td>Asphericity:</td>
<td>Anterior aspheric surface with aberration-neutral technology</td>
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<tr>
<td>Optic Edge Design:</td>
<td>Amon-Apple 360° enhanced square edge</td>
</tr>
<tr>
<td>Haptic Angulation:</td>
<td>0°, uniplanar</td>
</tr>
<tr>
<td>Haptic Style:</td>
<td>Open loop with anti-vaulting haptic (AVH) technology</td>
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#### Estimated Constants for Optical Biometry

<table>
<thead>
<tr>
<th>SRK/T</th>
<th>Haigis</th>
<th>HofferQ</th>
<th>Holladay</th>
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<tbody>
<tr>
<td>A-constant</td>
<td>a0</td>
<td>a1</td>
<td>a2</td>
</tr>
<tr>
<td>Aspheric</td>
<td>118.6</td>
<td>1.17</td>
<td>0.40</td>
</tr>
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</table>

For Contact Ultrasound, the estimated A-constant for Aspheric is 118.0.

Please note that the constants indicated for all Rayner lenses are estimates and are for guidance purposes only. Surgeons must always expect to personalize their own constants based on initial patient outcomes, with further personalization as the number of eyes increases.
**RayOne™ Aspheric fully preloaded IOL injection system**

**01**
![Secondary Blister Pack](Image)

Completely peel back the lid of the first blister pack.

**02**
![Primary Blister Pack](Image)

Carefully peel back the lid half way down the second blister tray.

**03**

Carefully drain the saline from the blister tray and peel off the remaining lid. Do not remove the injector from the blister tray. Do not wait more than 3 minutes before adding OVD - due to the risk of dehydration.

**04**

Insert the OVD cannula into the opening marked with an arrow on the cartridge and apply sufficient OVD to completely fill the cartridge.

**05**

Ensure both clips “Click”

Keep the injector in the tray and close the cartridge firmly together by pushing the moving half of the cartridge (labelled 2) against the fixed half until you hear it click closed. Check both clips have “clicked” shut and secured the cartridge.

**06**

Gently lift out the injector from the tray.

**07**

Nozzle

Press the plunger in a slow and controlled manner. In the case of IOL rotation during ejection from the nozzle, gently rotate the injector in the opposite direction to counteract any movement.

**08**

Stop depressing the plunger when the IOL exits the nozzle. Discard the injector after use. Following implantation, irrigate/aspirate to eliminate any OVD residues from the eye, especially behind the IOL.