Trifocal IOLs
When expectations and outcomes align
Leading the way in ophthalmic innovation

Rayner manufactured the world’s first IOL in 1949, and has remained at the forefront of innovation for over 70 years, focused on providing you and your patients with the best IOLs and ophthalmic solutions - 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.

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1910</td>
<td>Rayner is founded in London, UK.</td>
</tr>
<tr>
<td>1949</td>
<td>Rayner makes the world’s first IOL.</td>
</tr>
<tr>
<td>1979</td>
<td>Rayner has the first IOL approved by the US FDA.</td>
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</tbody>
</table>
| 2007 | Rayner launches:  
• The first multifocal IOL  
• The first pseudophakic supplementary IOL  
• The first FDA approved IOL from a non-American manufacturer in two decades. |
| 2016 | • Brand new HQ and state-of-the-art manufacturing facility opens in Worthing, UK.  
• RayOne fully preloaded IOL system is unveiled at the 2016 ESCRS congress.  
• Rayner acquires Moorfields Pharmaceuticals. |
| 2017 | RayOne Trifocal premium preloaded IOL is launched. |
| 2018 | • RayOne Hydrophobic and RayOne Toric preloaded IOLs are released.  
• Sulcoflex Trifocal, the world’s first supplementary trifocal IOL is launched.  
• AEON eye drop family is introduced, designed specifically for before and after surgery. |
| 2019 | • RayPRO digital platform for patient reported outcomes data is released.  
• RayOne Trifocal Toric is launched, completing Rayner’s trifocal IOL family. |
| 2020 | RayOne Enhanced Monovision preloaded IOL is launched. |
Trifocal IOL solutions for all your patients

Patient expectations from lens surgery are changing, with an increasing desire to be spectacle free as they continue to lead highly active and social lifestyles until much later in life.

Whether your patients are having cataract surgery or visiting you for refractive enhancement, our complete family of trifocal IOLs are clinically proven to provide them with the best visual outcomes.

- RayOne Trifocal preloaded IOL – for placement in the capsular bag
- RayOne Trifocal Toric preloaded IOL – for placement in the capsular bag and correction of preoperative corneal astigmatism
- Sulcoflex Trifocal supplementary IOL – for placement in the ciliary sulcus, with optional correction of refractive change or error

Has the patient had cataract surgery yet?

- Yes
  - Does the patient have any refractive change or error?
    - Yes
      - Available -3.0 D to +3.0 D
      - Duet
    - No
      - No

- No
  - Are you confident about the patient’s suitability for a trifocal lens?
    - Yes
      - Does the patient have greater than 1.0 D of preoperative corneal astigmatism?
        - Yes
          - Duet
        - No
          - Duet
    - No
      - Duet
Optimised diffractive design

Our family of trifocal IOLs use Rayner’s patented diffractive profile that was designed in partnership with a leading European technology institute.

This new design of diffractive technology is the most advanced optic in our history and possibly the most advanced in the industry.

The diffractive surface is a construct of two profiles to form our patented design:

Graphical representations only of diffractive surface pattern.

Rayner’s diffractive trifocal design has fewer rings on the optic surface than many trifocal IOLs for **reduced potential visual disturbances and improved night vision.**

**FEATURES**
- 16 diffractive rings/steps
- 4.5 mm diffractive zone
- >4.5 mm monofocal, distance

**PATIENT BENEFITS**
- Reduces visual disturbances
- Developed to be less dependent on pupil size or lighting conditions
- Improves distance vision in mesopic condition
Our patented diffractive step trifocal technology reduces light loss to only 11%

- 89% of light is transmitted to the retina with a pupil of 3.0 mm
- Half the light is allocated for distance
- Remaining light is divided between near and intermediate vision

Our patented diffractive step trifocal technology reduces light loss to only 11%

Comfortable transition from near to distance activities

Our trifocal optic improves intermediate visual acuity, enabling patients to feel more comfortable transitioning from near to distance activities
Clinically-proven and industry leading trifocal technology

Comparable outcomes

In a retrospective study of RayOne Trifocal and Sulcoflex Trifocal in 40 eyes, the defocus curve shows comparable visual acuity results and reports similar outcomes.¹

Less photic phenomena

In a prospective study of 60 eyes, a statistically significant difference favouring the RayOne Trifocal versus the FineVision POD F was achieved in an objective evaluation of photic phenomenon.²
Less photic phenomena and increased patient satisfaction

In a prospective comparative study of 64 eyes of 32 patients, the RayOne Trifocal group is associated with better scores for glare, symptoms and near and distance VA against the PanOptix Trifocal group.¹⁵

100% spectacle independence

In a prospective study of 16 eyes implanted with RayOne Trifocal, 100% of patients achieved spectacle independence and agreed they would have the operation again at 1 month follow up.³

For me, the most important question for judging patient satisfaction asks...

‘Would you repeat the treatment with the same procedure?’

and 100% said

‘YES’

– Fernando Llovet-Osuna, MD, PhD, Medical Director of Clínica Baviera, Spain
RayOne Trifocal

STATS

- Industry leading 11% light loss²
- Diffractive +3.5 D near add, +1.75 D intermediate add
- Fully preloaded from 0.0 D to +30.0 D (0.5 D increments)

FEATURES & BENEFITS

- Aberration-neutral aspheric optic for visual quality and acuity in all light conditions
- Amon-Apple enhanced square edge for minimal PCO 1.7% at 24 months⁴
- Based on proven haptic technology for excellent stability⁵
- Zero glistenings
- Biocompatible hydrophilic acrylic material with a long safety record - over 7.5 million lenses sold since 2003
- Fully preloaded across the entire power range

Proven haptic technology for excellent stability

Any rotation, tilt or decentration of a multifocal lens could affect patient outcomes and cause photopic disturbances. Our anti-vaulting haptic technology gives proven rotational and centrical stability, plus excellent fixation in the capsular bag:

- **Superb centration** - Average offset of only 0.08 mm 3 to 6 months after surgery⁵
- **Excellent rotational and torsional stability** - 1.83° mean IOL rotation 3 to 6 months after surgery⁵

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<table>
<thead>
<tr>
<th>STAGE 1</th>
<th>STAGE 2</th>
<th>STAGE 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.5mm</td>
<td>10mm</td>
<td>9.5mm</td>
</tr>
</tbody>
</table>

**The Queen’s Awards for Enterprise:**

**Innovation 2020**
RayOne Trifocal Toric

FEATURES & BENEFITS

• Correct more of your patients, even those with significant corneal astigmatism.

• Proven rotational stability and centration with predictable, sustainable and accurate visual results.

• Aberration-neutral aspheric optic for visual quality and acuity in all light conditions.

• Fully preloaded across the entire power range.

• Simplified range of IOL plane cylinders:
  +0.75 D
  +1.5 D
  +2.25 D
  +3.0 D
  +3.75 D
  +4.5 D

STATS

• 1.83° mean post-operative rotation at 3 to 6 months.

• 100% lenses rotated ≤5°.

• 0.08 mm average centration offset at 3 to 6 months.

Prevalence of corneal astigmatism prior to cataract surgery

n = 6,000. Warren E. Hill, MD. Keratometry database.
RayOne injector

**TWO-STEP SYSTEM**
- Easy to use
  - Minimal learning curve
  - Reduces error
- Efficient IOL delivery time
  - Designed for repeatability
  - Reduces operating time
- **Step 1**: Insert OVD into cartridge via port
- **Step 2**: Lock cartridge ready for implantation

**FEATURES & BENEFITS**
- 1.65 mm nozzle for sub 2.2 mm incision
- Smallest fully preloaded injector nozzle
  - Ease of insertion
  - Enables true micro incision
- Ergonomic design for ease of handling
- Single handed plunger with minimal force required
- Parallel sided for minimal stretch
  - Sub 2.2 mm delivery
  - Maintains incision architecture

**Unique patented Lock & Roll technology for consistent delivery**
- Rolls the lens to under half its size before injection
  - Consistent, smoother delivery
  - Reduces insertion forces
- Fully enclosed cartridge with no lens handling
  - Reduces the risk of lens damage
  - Minimises chance of contamination

**Lock & Roll technology**
Consistently locked and rolled to under half its size in one simple action
Sulcoflex Trifocal

FEATURES & BENEFITS

- Large 14.0 mm overall length with undulating haptics, designed for stable fixation in the ciliary sulcus
- Unique undulating round edge haptic design with 10° angulation
- Excellent centration stability compared to capsular bag fixated multifocal IOLs
- Smooth undulating haptics to minimise the risk of adverse tissue reaction in the sulcus

*Contraindicated for implantation into eyes with multifocal capsular bag IOLs.

INDICATIONS

- Presbyopia (DUET procedure)
- Pseudophakic presbyopia (secondary enhancement)
- Post-surgical ametropia
- Patients who have experienced a change in their post-op refraction

Designed to avoid the potential problems of conventional “piggy-back” IOLs

- Unique posterior concave surface minimises the possibility of interaction with the primary IOL
- Reduced likelihood of unwanted photopic effects
- Reduced refractive error with hyperopic defocus

* Contraindicated for implantation into eyes with multifocal capsular bag IOLs.

Physical contact between the two IOLs minimised.

Iris • Sulcoflex

Sulcoflex • IOL
Sulcoflex Trifocal DUET procedure

What is a DUET procedure?

The Sulcoflex Trifocal DUET procedure involves the sequential implantation of a primary capsular bag IOL and a supplementary Sulcoflex Trifocal sulcus IOL. This is done as a planned DUET procedure during the initial cataract surgery.

The DUET is an easy procedure, adding little time to the overall cataract surgery, yet offers an elegant and adjustable solution.

How do I perform a DUET procedure?

During the DUET procedure the capsular bag IOL is implanted first and treats the sphere - and where required cylinder - correction power for distance vision.

Then a plano Sulcoflex Trifocal is implanted which features our patented trifocal optics with a +3.50 D add for near vision and +1.75 D add for intermediate vision.

Combining the two lenses provides the patient with an opportunity for a spectacle free solution.

Injector

Implantation of the Sulcoflex Trifocal is made easy with the Medicel ACCUJECT 1.80-1 (LP604540) - recommended and provided by Rayner.
A wider patient selection with the Sulcoflex Trifocal DUET procedure

There are several reasons why a patient may not be suitable for a capsular bag multifocal IOL. Through the option of reversibility, the Sulcoflex Trifocal DUET procedure may offer a solution for these patients.

- Works with any monofocal or toric primary capsular bag IOL
- Available in 0.25 D increments from -3.0 to +3.0 D

Exploiting the benefits of reversibility and adjustability

Unlike capsular bag multifocal IOLs or refractive laser treatments, the Sulcoflex Trifocal DUET procedure is easily reversed. Refractive change or surprise cannot be predicted, and nor can a failure to neuroadapt. Through the DUET procedure, the optic system can be easily adjusted with a different Sulcoflex Trifocal or converted back to monofocality in a straightforward procedure.

- Plan for excellence with a simultaneous implantation
- Treat ametropia after cataract surgery
- Reversible – more flexibility for you and your patient

It may seem counter-intuitive to implant a lens in anticipation of its removal, but for premium channel cataract and refractive surgeons, the ability to offer patients the benefits of a specialist lens knowing that the procedure can be reversed at a later date, is highly reassuring.

The Sulcoflex Trifocal DUET procedure empowers surgeons with the ability to offer refractive treatments to their patients without needing to invest in expensive laser equipment. This cost-efficient treatment option can easily be incorporated into any existing cataract surgery environment.

A new opportunity for pseudophakic patients

There are estimated to be 100 million pseudophakic patients globally, with approximately 92% having had a monofocal IOL implanted (Market Scope 2018). Although monofocal IOLs improve distance vision, patients are typically left spectacle dependent for tasks involving near and intermediate vision. With personal technology playing an important role in today’s world and cataract patients remaining highly active until later in life, many are demanding the opportunity to become spectacle free.

Cataract patients may have been unaware of the trifocal IOL options available to them at the time of their original surgery. Sulcoflex Trifocal can be implanted any time after cataract surgery, irrespective of the monofocal or toric IOL in the capsular bag, giving pseudophakic patients the opportunity to perform near and intermediate distance tasks without the need for spectacles. Due to its reversibility, Sulcoflex Trifocal also allows patients that were previously deemed potentially unsuitable for trifocal IOLs to be re-evaluated.

Sulcoflex Trifocal creates new surgery opportunities for cataract and refractive surgeons, allowing them to offer a large population of pseudophakic patients the chance to become spectacle free with an adjustable and reversible solution.

For more information, visit the Sulcoflex Trifocal patient website www.sulcoflex.com
When considering a solution for presbyopia, what is important to you?

With the Rayner Sulcoflex platform, you can expect the following:

- Exceptional light usage
- Ease of use
- Efficacy and patient outcomes
- Versatility to treat a wider range of patients
- An adjustable solution for peace of mind
- Increased accuracy with quarter dioptre steps

**Predictability**
- Proven to provide better centration compared to capsular bag multifocal IOLs
- Predictable refractive outcomes; high visual acuity
- High patient satisfaction
- Low complication rate
- Stable long-term refractive results

**Reduced surgical risk associated with IOL exchange**
- Less surgical trauma than primary IOL exchange
- Avoids sometimes difficult removal of fibrosed, fixated primary implant
- Allows for implantation reversibility

“The world’s first trifocal supplementary IOL may be used in routine cataract procedures (DUET) or in pseudophakes for presbyopic correction. This IOL concept allows the surgeon to adjust the optical system to any unpredictable situation in the future.”

Professor Michael Amon MD, Head of the Department of Ophthalmology at the Academic Teaching Hospital of St John, Vienna, Austria

Support the best visual outcomes with...

**AEON**
An eye drop family designed specifically to support visual outcomes and patient satisfaction before and after surgery.

Learn more at rayner.com/aeon

**RayPRO**
A free mobile and web-based digital platform that collects insightful Patient Reported Outcomes (PROs) over three years.

Learn more at rayner.com/raypro
### Technical information

<table>
<thead>
<tr>
<th>Model Name</th>
<th>RayOne Trifocal RAO603F</th>
<th>RayOne Trifocal Toric RAO613Z</th>
<th>Sulcoflex Trifocal IOL703F</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Power Range</strong></td>
<td>Trifocal: 0.0 D to +30.0 D (0.5 D increments)</td>
<td>Trifocal Toric: Spherical Equivalent: +6.0 D to +30.0 D (0.5 D increments)</td>
<td>-3.0 D to +30.0 D (0.25 D increments)</td>
</tr>
<tr>
<td></td>
<td>Trifocal: +0.75 D, +1.5 D, +2.25 D, +3.0 D, +3.75 D, +4.5 D</td>
<td>Cylinders: +3.5 D near add and +1.75 D intermediate add at the IOL plane</td>
<td>Trifocal, diffractive, +3.5 D near add and +1.75 D intermediate add at the IOL plane</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Material</th>
<th>Single piece Rayacryl hydrophilic acrylic</th>
<th>Single piece Rayacryl hydrophilic acrylic</th>
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<tbody>
<tr>
<td>Water Content</td>
<td>26% in equilibrium</td>
<td>26% in equilibrium</td>
</tr>
<tr>
<td>UV Protection</td>
<td>Benzophenone UV absorbing agent</td>
<td>Benzophenone UV absorbing agent</td>
</tr>
<tr>
<td>UV Light Transmission</td>
<td>UV 10% cut-off is 380 nm</td>
<td>UV 10% cut-off is 380 nm</td>
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<tr>
<td>Refractive Index</td>
<td>1.46</td>
<td>1.46</td>
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<tr>
<td>ABBE</td>
<td>56</td>
<td>56</td>
</tr>
<tr>
<td>Overall Diameter</td>
<td>12.5 mm</td>
<td>14 mm</td>
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<tr>
<td>Optic Diameter</td>
<td>6 mm</td>
<td>6.5 mm</td>
</tr>
<tr>
<td>Optic Shape</td>
<td>Biconvex (positive powers)</td>
<td>Anterior convex, posterior concave</td>
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<tr>
<td>Asphericity</td>
<td>Aberration-neutral technology</td>
<td>Aberration-neutral technology</td>
</tr>
<tr>
<td>Optic Edge Design</td>
<td>Amon-Apple 360° enhanced square edge</td>
<td></td>
</tr>
<tr>
<td>Haptic Angulation</td>
<td>0°, uniplanar</td>
<td>10° Posterior</td>
</tr>
<tr>
<td>Haptic Style</td>
<td>Anti-Vaulting Haptic (AVH) technology</td>
<td>Undulating and rounded C-loop haptics</td>
</tr>
<tr>
<td>Estimated constant for power calc.</td>
<td></td>
<td>Expected lens position 4.5 mm</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>RayOne delivery system</th>
<th>Single use, fully preloaded IOL injection system</th>
<th>Medicel ACCUJECT 1.80-1 (LP604540)</th>
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</thead>
<tbody>
<tr>
<td>Incision Size</td>
<td>1.65 mm nozzle for sub 2.2 mm incision</td>
<td>1.8 mm nozzle for sub 2.2 mm incision</td>
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<tr>
<td>Bevel Angle</td>
<td>45°</td>
<td>35°</td>
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<tr>
<td>Lens Delivery</td>
<td>Single handed plunger</td>
<td>Single handed plunger</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>
<th>Holladay II</th>
<th>Barrett Universal II</th>
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</thead>
<tbody>
<tr>
<td>A-constant</td>
<td>a0</td>
<td>a1</td>
<td>a2</td>
<td>pACD</td>
<td>SF</td>
</tr>
<tr>
<td>RayOne Trifocal &amp; RayOne Trifocal Toric</td>
<td>118.6</td>
<td>1.044</td>
<td>0.40</td>
<td>0.10</td>
<td>5.32</td>
</tr>
</tbody>
</table>

For Contact Ultrasound, the estimated A-constant 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 personalise their own constants based on initial patient outcomes, with further personalisation as the number of eyes increases.

For Sulcoflex Trifocal lens calculations, visit www.raytrace.rayner.com

### References:
