

Trifocal IOLs

When expectations and outcomes align

SULCOflex
TRIFOCAL

RayOne
TRIFOCAL

RayOne
TRIFOCAL
TORIC

 Rayner

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.

1910

Rayner is founded in London, UK.

1949

Rayner makes the world's first IOL.

1979

Rayner has the first IOL approved by the US FDA.

2007

- Rayner launches:
- The first multifocal toric 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.

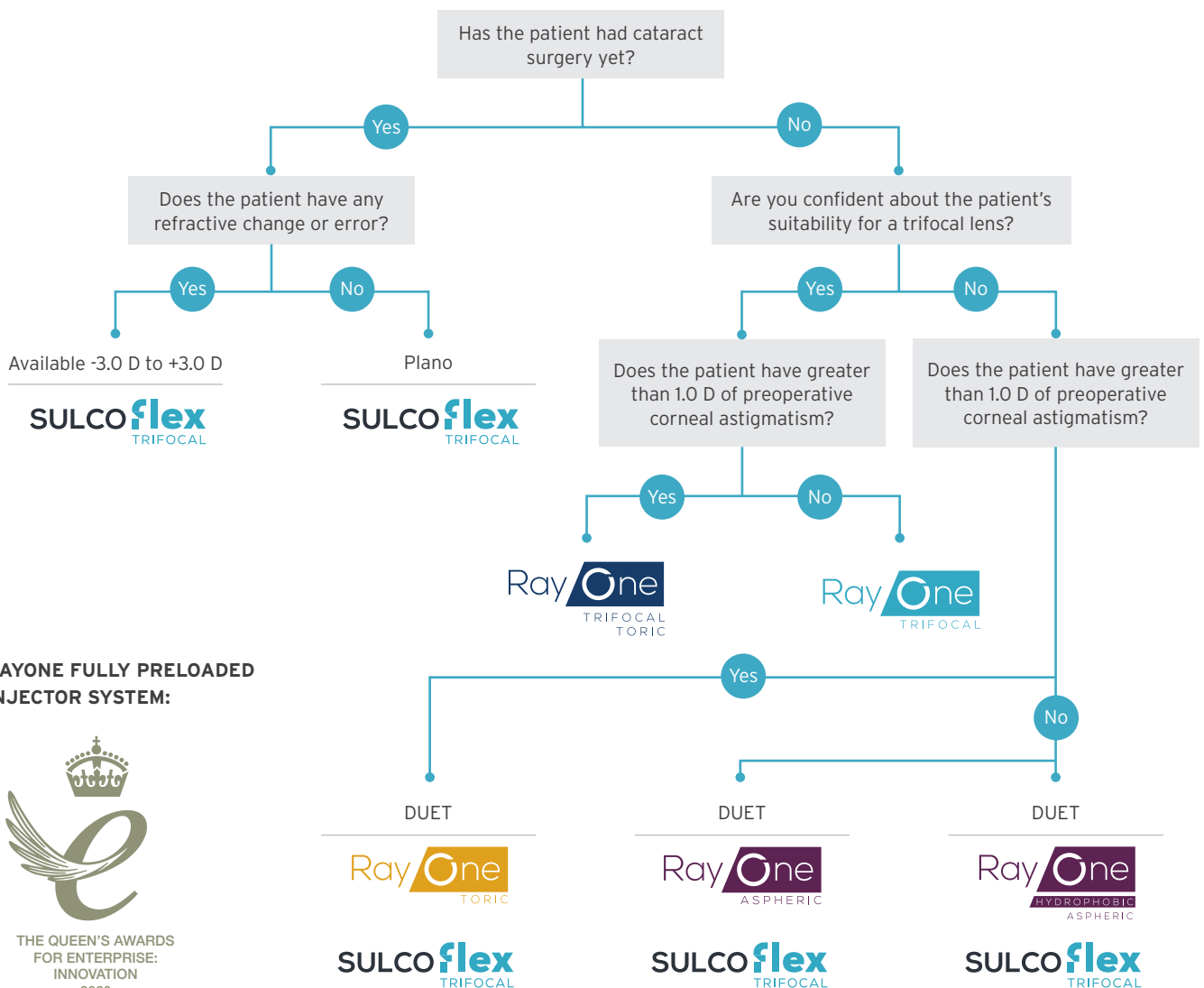


Trifocal IOL solutions for all your patients

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



RAYONE FULLY PRELOADED INJECTOR SYSTEM:



THE QUEEN'S AWARDS
FOR ENTERPRISE:
INNOVATION
2020

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.

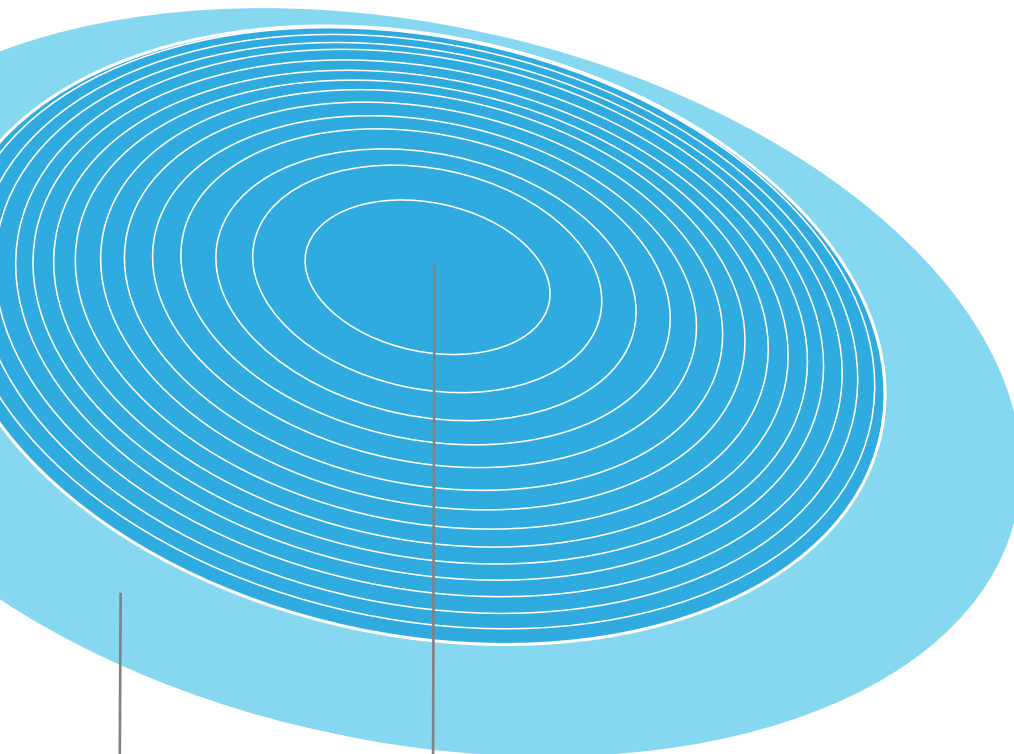
This new design of diffractive technology is the most advanced optic in our history and possibly the most advanced in the industry.

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.**



>4.5 mm
distance zone

4.5 mm diffractive
trifocal zone

FEATURES

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

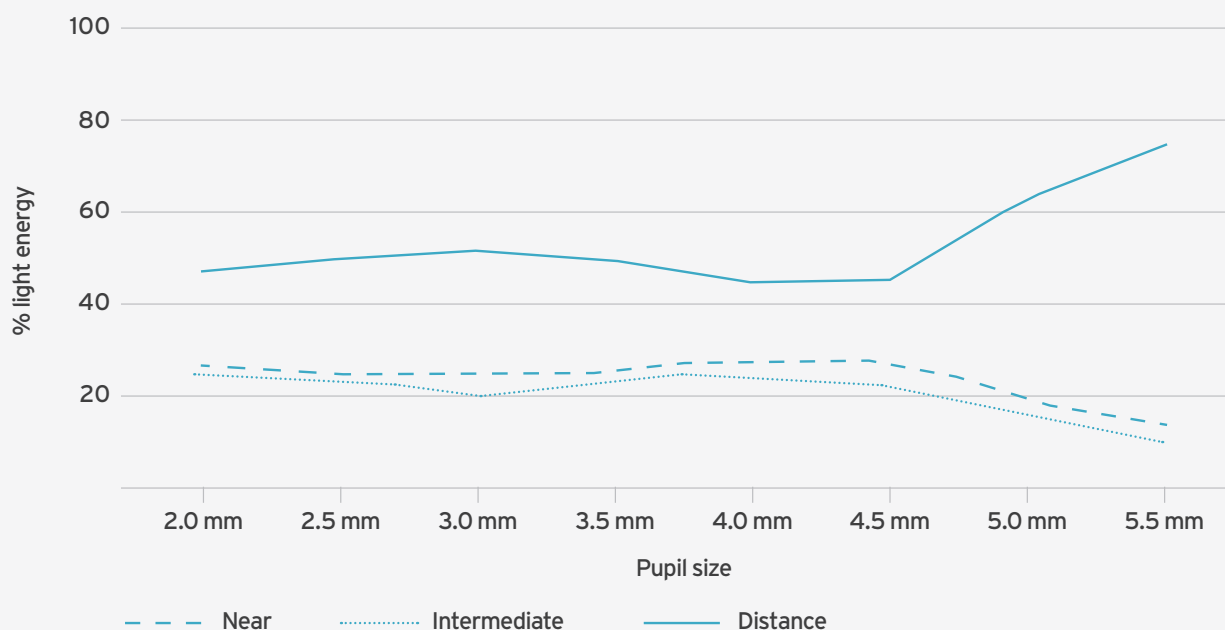
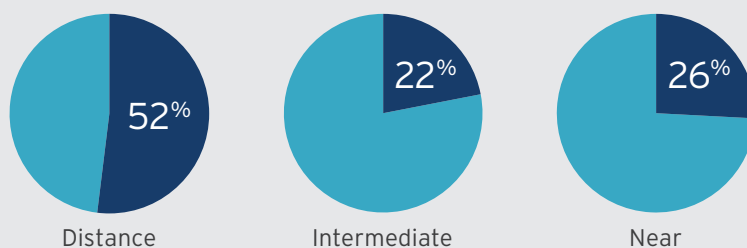
PATIENT BENEFITS

- 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%

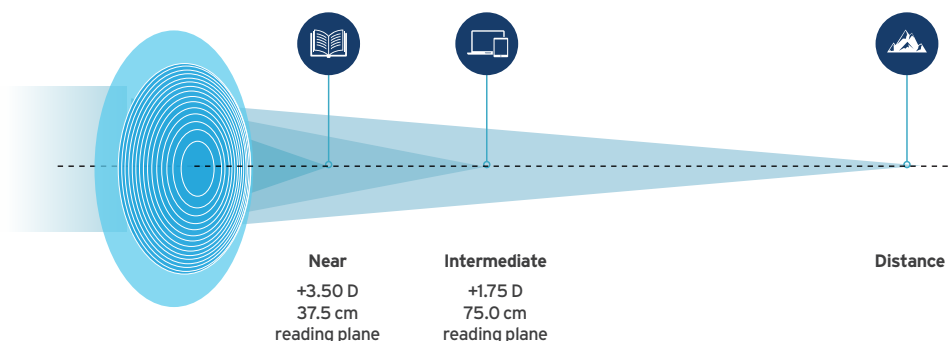
- 89% of light is transmitted to the retina with a pupil of 3.0 mm
- Half the light is allocated for distance
- Remaining light is divided between near and intermediate vision

Light energy split with a 3.0 mm pupil:



Comfortable transition from near to distance activities

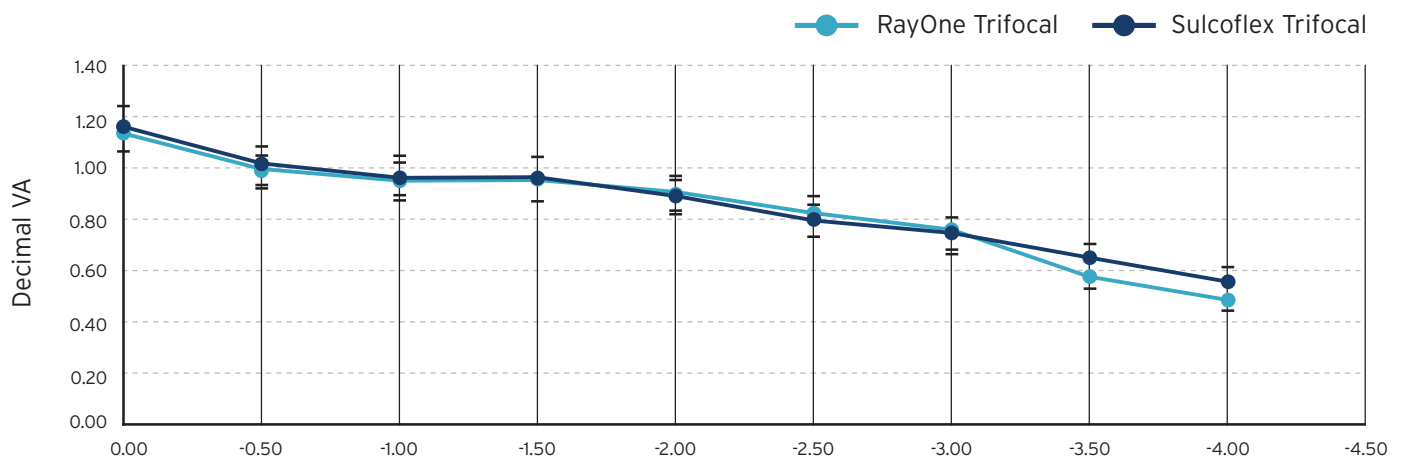
Our trifocal optic improves intermediate visual acuity, enabling patients to feel more comfortable transitioning from near to distance activities



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

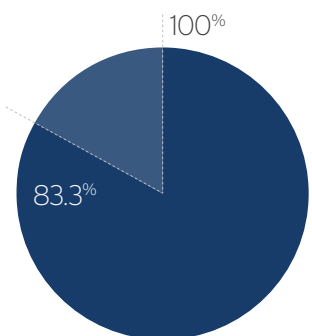


EXCELLENT REFRACTIVE PREDICTABILITY

At three months,

100%

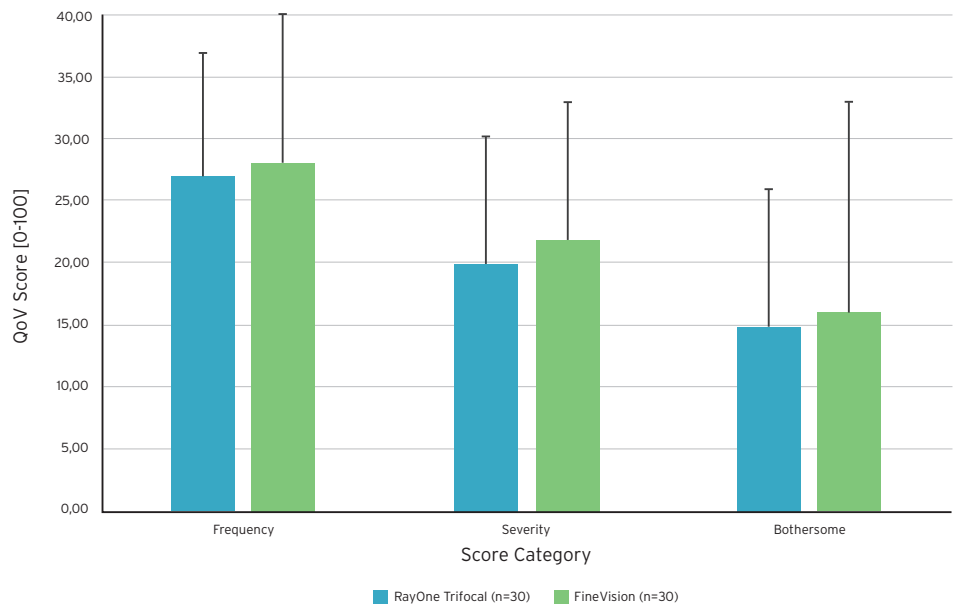
of eyes within $\pm 0.5D$ of the target SEQ²



vs. 83.3% with PhysIOL FineVision POD F

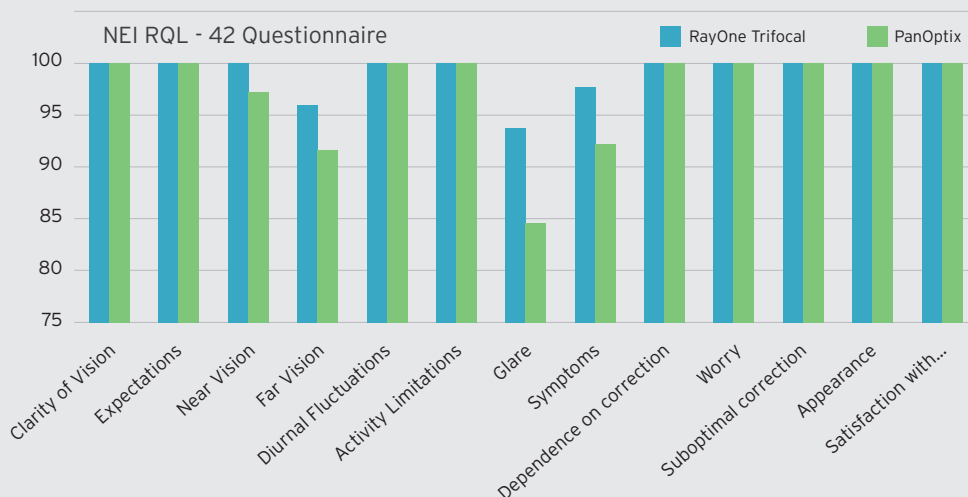
Less photic phenomena

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



In a prospective comparative study of 60 eyes²

40% vs. 67%
Glare

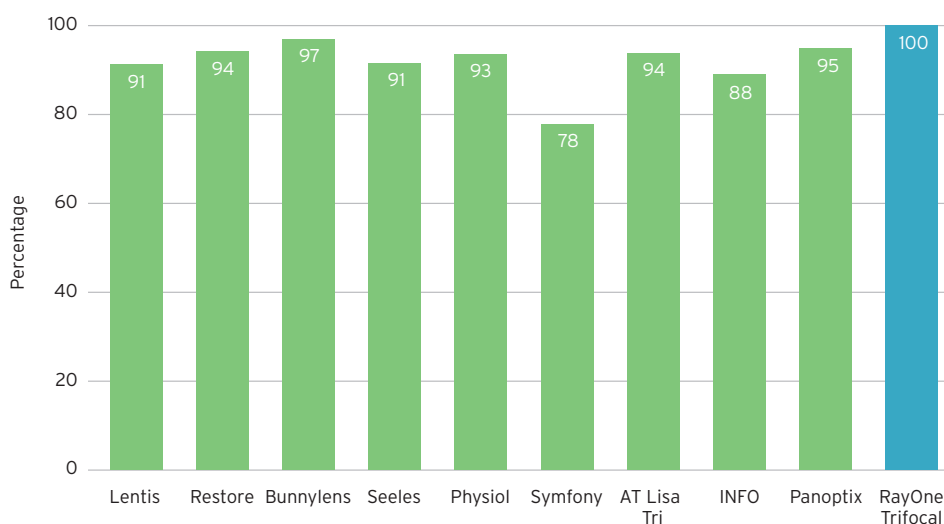
40% vs. 53%
Halos

7% vs. 33%
Difficulties in depth perception

RayOne Trifocal
FineVision POD F

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, Spain¹

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)

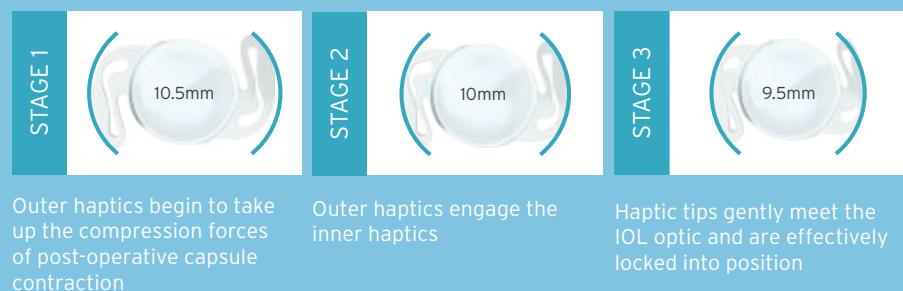
FEATURES & BENEFITS

- 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

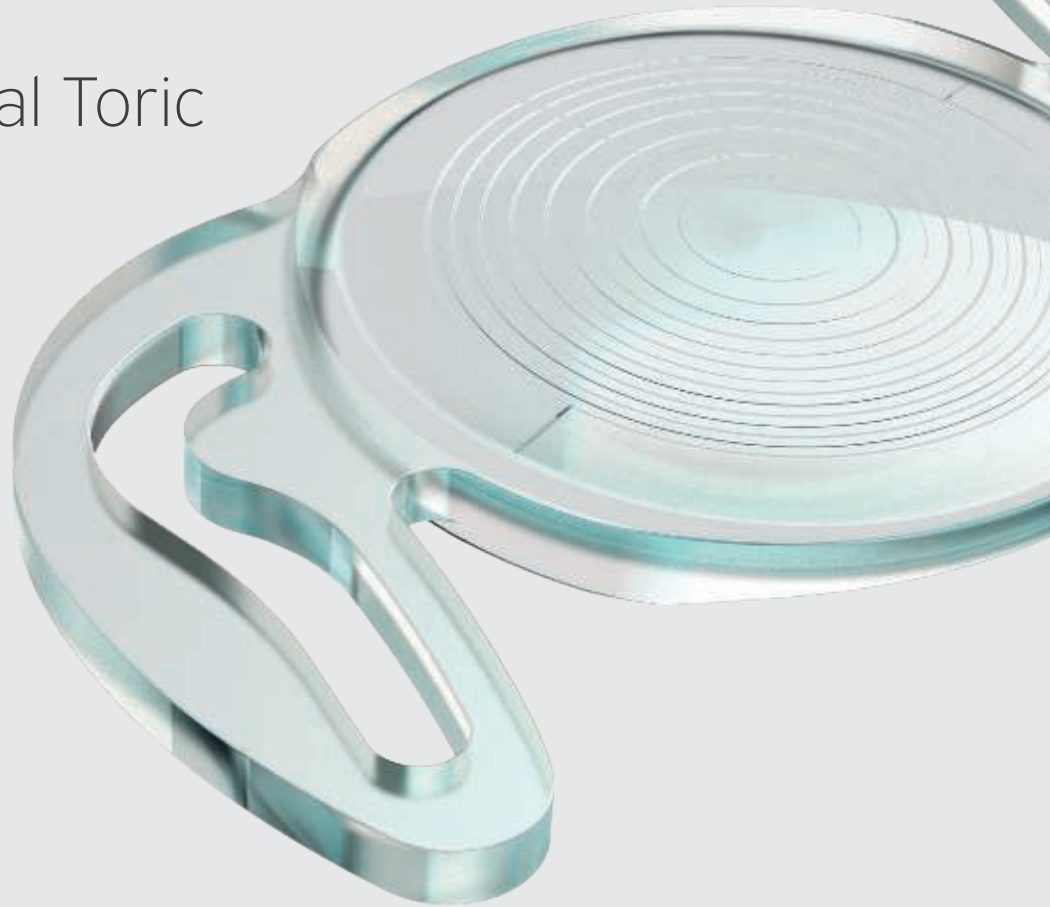
Proven haptic technology for excellent stability

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 centration 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



RayOne Trifocal Toric



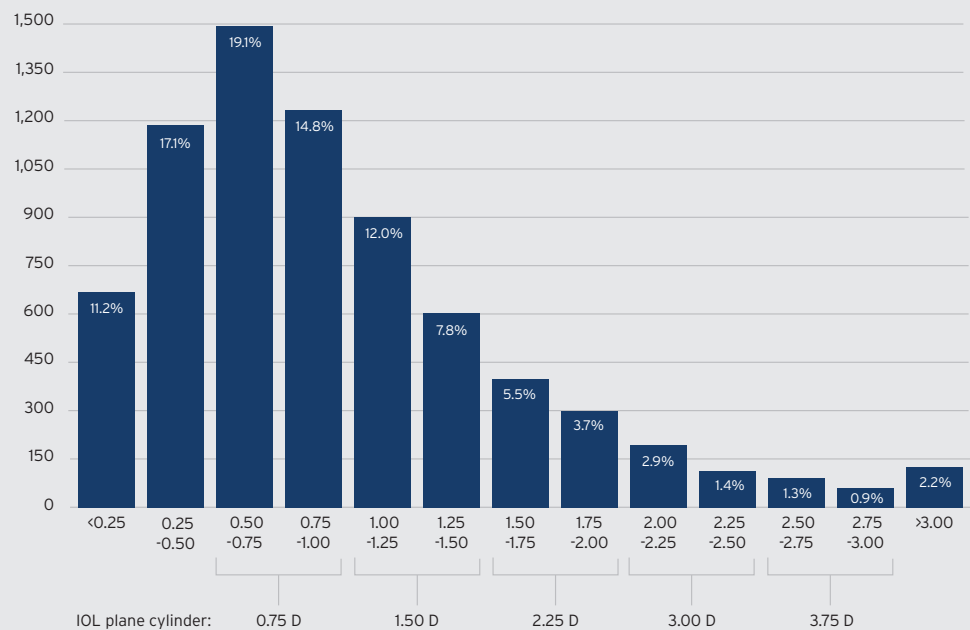
STATS

- 1.83° mean post-operative rotation at 3 to 6 months⁵
- 100% lenses rotated $\leq 5^\circ$ ⁵
- 0.08 mm average centration offset at 3 to 6 months⁵

FEATURES & BENEFITS

- Correct more of your patients, even those with significant corneal astigmatism.
- Proven rotational stability and centration⁵ 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

Prevalence of corneal astigmatism prior to cataract surgery



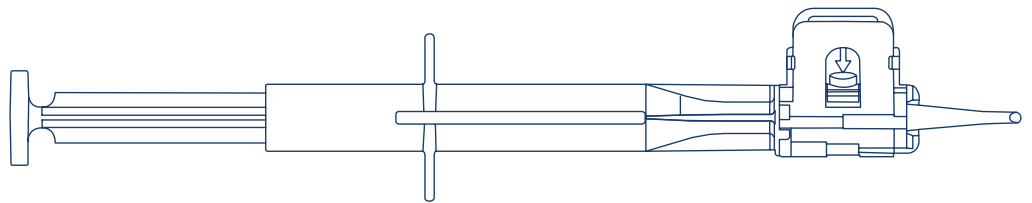
n = 6,000. Warren E. Hill, MD. Keratometry database.

RayOne injector



TWO-STEP SYSTEM

- Easy to use⁶
 - i. Minimal learning curve
 - ii. Minimises error
- Efficient IOL delivery time⁶
 - i. Designed for repeatability
 - ii. 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
 - i. Ease of insertion
 - ii. Enables true micro incision
- Ergonomic design for ease of handling
- Single handed plunger with minimal force required
- Parallel sided for minimal stretch
 - i. Sub 2.2 mm delivery
 - ii. Maintains incision architecture

Unique patented Lock & Roll technology for consistent delivery

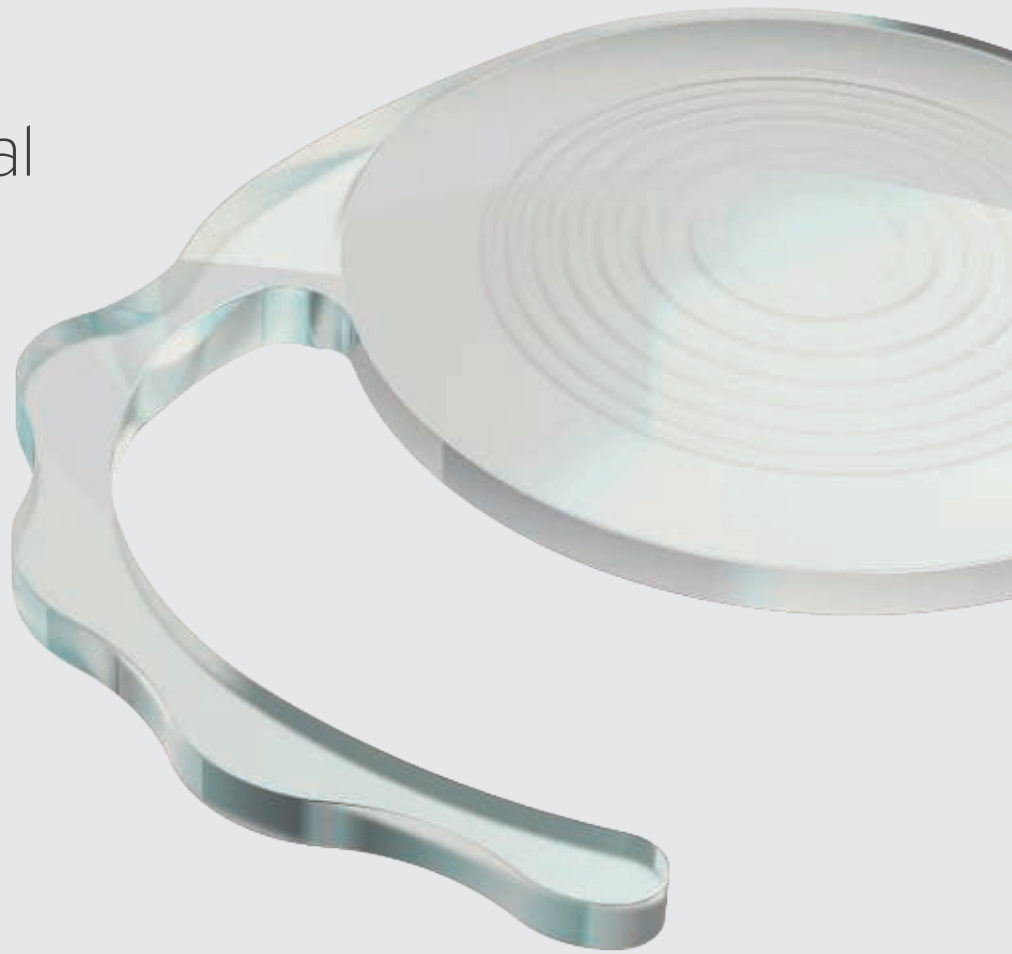
- Rolls the lens to under half its size before injection
 - i. Consistent, smoother delivery
 - ii. Reduces insertion forces
- Fully enclosed cartridge with no lens handling
 - i. Reduces the risk of lens damage
 - ii. Minimises chance of contamination

Lock & Roll technology



Consistently locked and rolled to under half its size in one simple action

Sulcoflex Trifocal



INDICATIONS^{8,12}

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

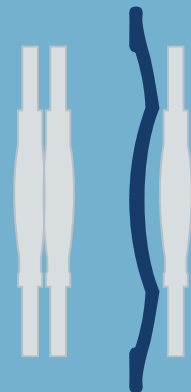
FEATURES & BENEFITS

- 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 IOLs⁷
- Smooth undulating haptics to minimise the risk of adverse tissue reaction in the sulcus

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

Designed to avoid the potential problems of conventional "piggy-back" IOLs^{8,9,10}

- 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



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 MediceI ACCUJECT 1.80-1 (LP604540) - recommended and provided by Rayner.



MEDICEI ACCUJECT

Single handed injector with soft tip plunger. ACCUJECT's 1.8 mm nozzle tip allows for a sub 2.2 mm incision.



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.

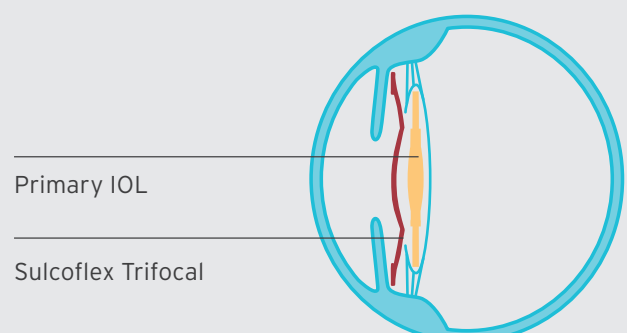
A new opportunity for pseudophakic patients

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 use¹¹
- Efficacy and patient outcomes¹¹
- Versatility to treat a wider range of patients¹²
- An adjustable solution for peace of mind
- Increased accuracy with quarter dioptre steps

Predictability^{7,8,12}

- Proven to provide better centration compared to capsular bag multifocal IOLs
- Predictable refractive outcomes; high visual acuity

High patient satisfaction¹²

- Low complication rate
- Stable long-term refractive results

Reduced surgical risk associated with IOL exchange^{8,9,13}

- 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.

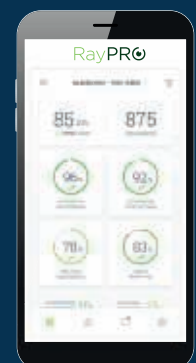
Learn more at
rayner.com/aeon



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

Model Name	RayOne Trifocal RA0603F	RayOne Trifocal Toric RA0613Z	Sulcoflex Trifocal IOL703F
Power Range	Trifocal: 0.0 D to +30.0 D (0.5 D increments) Trifocal Toric: Spherical Equivalent: +6.0 D to +30.0 D (0.5 D increments) Cylinders: +0.75 D, +1.5 D, +2.25 D, +3.0 D, +3.75 D, +4.5 D Trifocal, diffractive, +3.5 D near add and +1.75 D intermediate add at the IOL plane		-3.0 D to +3.0 D (0.25 D increments) Trifocal, diffractive, +3.5 D near add and +1.75 D intermediate add at the IOL plane

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

	RayOne delivery system	Sulcoflex Trifocal delivery system
Injector Type	Single use, fully preloaded IOL injection system	MediceI ACCUJECT 1.80-1 (LP604540)
Incision Size	1.65 mm nozzle for sub 2.2 mm incision	1.8 mm nozzle for sub 2.2 mm incision
Bevel Angle	45°	35°
Lens Delivery	Single handed plunger	Single handed plunger

Estimated Constants for Optical Biometry	SRK/T	Haigis			HofferQ	Holladay	Holladay II	Barrett Universal II	
	A-constant	a0	a1	a2	pACD	SF	pACD	LF	DF
RayOne Trifocal & RayOne Trifocal Toric	118.6	1.044	0.40	0.10	5.32	1.56	5.32	1.67	3.5

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:

1. Eurotimes Supplement Feb 2019. RayOne Trifocal & Sulcoflex Trifocal. 2. Ferreira TB and Ribeiro FJ. J Refract Surg. 2019;35(7):418-425. 3. De Lange J. Ophthalmology Times Europe article March 2019. 4. Mathew RG and Coombes AGA. Ophthalmic Surg Lasers Imaging. 2010 Nov-Dec;41(6):651-5. 5. Bhogal-Bhamra GK et al. Journal of Refractive Surgery. 2019;35(1):48-53. 6. Nanavaty MA and Kubrak-Kisza M. J Cataract Refract Surg. 2017 Apr;43(4):558-563. 7. Prager F et al. J Cataract Refract Surg. 2017;43(5):643-647. 8. Amon MI. Cataract Refract Surg Today Europe. 2009;56-9. 9. Kahraman G and Amon M. J Cataract Refract Surg. 2010 Jul;36(7):1090-4. 10. Manzouri B et al. Asia-Pacific Journal of Ophthalmology. Vol 6, Number 4, July/August 2017. 11. Khan MI, Muhtaseb M. CRSTE June 2010. 12. Claoué et al. CRST Euro Supple. 2009. 13. Amon MI et al. ESCRS Euro Times Supple. 2012;2-3. 14. Khoramnia R et al. J Refract Surg. 2020;36(9):570-577. 15. Data on file, Jan 2021.



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MADE IN UK

