# Extending range without compromise





## An **enhanced** monofocal IOL delivering **up to 1.5 D of high quality** vision

Developed in collaboration with Professor Graham Barrett, RayOne EMV's truly non-diffractive optic utilises positive spherical aberration to uniquely extend vision whilst avoiding the problems that can arise with diffractive lenses.

RayOne EMV's range of focus can be extended further with a customisable offset for Enhanced Monovision outcomes.

### RayOne EMV and RayOne EMV Toric offers:



Increased range of focus: Up to 1.5 D<sup>1,4,6</sup> with an emmetropic target.



**High quality vision:** Truly non-diffractive IOL with monofocal levels of contrast sensitivity<sup>1</sup>, dysphotopsia<sup>2,5</sup> and high levels of patient satisfaction.<sup>3</sup>



**Enhanced Monovision**: Unique positive spherical aberration design provides a smoother transition between distance and near eyes.<sup>2,4</sup>



Now available on the rotationally stable RayOne toric platform.8



"For many years I have worked on optimising a lens for monovision, given that it accounts for nearly 30% of all surgeries. I collaborated with Rayner on bringing this lens to market as RayOne EMV, an exciting new product for all surgeons looking to treat presbyopia reliably"

Professor Graham Barrett, president of the Australasian Society of Cataract & Refractive Surgeons

### How does RayOne EMV work?

RayOne EMV is a truly non-diffractive IOL which does not use light splitting technology like many IOLs which increase depth of focus, resulting in low levels of dysphotopsia, similar to standard monofocal lenses.<sup>1</sup>

RayOne EMV has a unique patented aspheric optic that induces controlled positive spherical aberration.

Compared to a lens with zero spherical aberration, the carefully controlled positive spherical aberration induced by RayOne EMV spreads light along the visual axis, elongating the focal range from far into intermediate with up to 1.5 D of depth of focus (per lens on the spectacle plane).

Below shows an illustration of a lens with zero aberration and a small focal range (Figure 1), shown together with RayOne EMV with positive spherical aberration and a larger focal range (Figure 2).



Figure 1 Standard monofocal IOL with zero spherical aberration





Figure 2 spherical aberration Expected vision with a standard monofocal IOL



Expected vision with RayOne EMV



### Why is positive spherical aberration good for extending depth of focus?<sup>4</sup>

The positive spherical aberration induced by RayOne EMV complements the natural spherical aberration of the human cornea and gently increases depth of focus into the intermediate range - see illustrative Figure 3.

An equivalent negative spherical aberration IOL needs to first negate the positive spherical aberration of the cornea, then add even more negative spherical aberration to induce any required depth of focus improvements.

The total spherical aberration used on the RayOne EMV is therefore designed to be significantly less than for equivalent negative spherical aberration extended depth IOLs, and the RayOne EMV optical surface remains closer to spherical in form, thus making performance more consistent under normal tilt and decentration conditions.



Figure 3

### **Clinical results with RayOne EMV**

Since the launch of RayOne EMV in 2020, clinical data from across Europe has demonstrated that: 1.2.3.6.7

- RayOne EMV can provide spectacle independence in the distance to intermediate vision.
- RayOne EMV provides improvement in intermediate vision without compromising the binocular distance vision.
- RayOne EMV can help to improve your patients' near vision, particularly when used with monovision.

The following clinical results are from patients in the UK, Spain and Portugal during the months leading up to the commercial launch of RayOne EMV.<sup>2</sup>

	Value		Acuity @ 1 month (LogMAR)	Snellen Approximation		
MONOVISION	Binocular UDVA	(n=18)	-0.03 ± 0.05	6/6 20/20		
	Dominant Eye UDVA	(n=18)	-0.02 ± 0.07	6/6 20/20		
	Binocular UIVA	(n=17)	0.08 ± 0.12	N8 @ 100 cm J1 / J2 @ 40 cm		
	Binocular UNVA	(n=5)	N6 Range, N4 – N10	6/9 20/32		



of patients reported spectacle independence at distance, intermediate and near



of patients reported no difficulty negotiating steps, stairs or curbs with no depth perception or contrast sensitivity issues reported



of patients reported no incidence of halo, glare, starbursts or haze



of patients reported being dysphotopsia free



Dr. Mariano Royo, Director of Ophthalmology at the Hospital San Rafael in Madrid, shared his clinical results of 22 eyes of 11 patients implanted with RayOne EMV at six months post-op and 70 eyes of 35 patients implanted with TECNIS Eyhance (Johnson & Johnson Vision). Bilateral emmetropia was targeted for all patients in both groups. The defocus curve below reports the binocular vision obtained using the best distance correction.<sup>6</sup>



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CLINICAL RESULTS In a double-arm, non-randomised prospective case series, RayOne EMV demonstrated excellent visual outcomes for distance and intermediate vision, and good visual acuity for near vision.<sup>1</sup>





MMETROPIA

"RayOne EMV can easily be the lens that helps surgeons go from being a standard lens surgeon to a premium lens surgeon. It is a natural, easy transition for most surgeons to make, and it provides patients with good quality distance and intermediate vision along with useful near vision for many, particularly with a mini-monovision approach."

Mr Allon Barsam, Consultant Ophthalmic Surgeon & Director at OCL Vision

Uncorrected distance visual acuity at 2 weeks postoperative<sup>7</sup>

Uncorrected

postoperative<sup>7</sup>

Uncorrected near visual acuity at 2 weeks

postoperative<sup>7</sup>

intermediate visual acuity at 2 weeks

Binocular UDVA LogMAR	Cumulative %			
-0.1	41.70%			
0	100%			
n=24 eyes				

Mean Binocular UDVA (LogMAR) -0.04 ±0.05

Binocular UIVA	Cumulative %		
N6	70%		
N8	100%		

n=20 eyes

Binocular UNVA	Cumulative %		
N5	20%		
N6	70%		
N8	100%		

n=20 eyes







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5

### **RayOne EMV & EMV Toric**



#### **KEY INFORMATION**

- Up to 1.5 Dincreased range of focus with an emmetropic target.<sup>1,4,6</sup>
- Low levels of contrast sensitivity<sup>1</sup> and dysphotopsia<sup>2,5</sup>, similar to standard monofocal lenses.
- Positive spherical aberration design provides a natural range of vision.<sup>2,4</sup>

#### DESIGNED TO PROVIDE:

- Smoother, blended transition between the eyes when compared to monovision with standard monofocals, maintaining binocular stereoacuity and reducing asthenopia.
- High quality spectacle-free distance vision.
- Reduced pupil dependency, for optimised performance under low light conditions.
- Reduced sensitivity to decentration and tilt compared to other IOL designs.
- Complements the eye's natural level of spherical aberration.
- Fully preloaded across the entire power range.



Blended edge region: Reduced longitudinal spherical aberration designed to maintain visual acuity and contrast sensitivity under mesopic conditions

#### CORRECT MORE OF YOUR PATIENTS, EVEN THOSE WITH SIGNIFICANT CORNEAL ASTIGMATISM

**ENHANCED** 

TORIC

MARKINGS

- Proven rotational stability and centration<sup>®</sup> with predictable, sustainable and accurate visual results
- Average offset of only 0.08 mm 3 to 6 months after surgery<sup>8</sup>
- 1.83° mean IOL rotation 3 to 6 months after surgery<sup>8</sup>
- Available in a wide range of IOL plane cylinders: +0.75 D to +4.5 D, in +0.75 D increments



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#### VACUOLE FREE MATERIAL FOR A GLISTENING FREE IOL

- Single piece IOL created from a homogeneous material free of microvacuoles<sup>9</sup>
- Compressible material for delivery through a 2.2 mm micro incision<sup>10</sup>
- Excellent handling characteristics with controlled unfolding within the capsular bag<sup>11</sup>
- Low silicone oil adherence<sup>12</sup>
- Excellent uveal biocompatibility<sup>13</sup>
- Hydrophilic acrylic material with low inflammatory response<sup>14</sup>

### 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.<sup>15,16</sup>

ND:YAG CAPSULOTO	MY RATES¹⁵	MEAN TIME TO ND:YAG CAPSULOTOMY <sup>15</sup>			
At 12 months	0.6%	9.3 ± 5.5 mths (range 2.6 - 22.7 mths)			
At 24 months 1.7%		Follow-up period: 5.3 - 29 mths			

Extremely low Nd:YAG capsulotomy rates, comparable with hydrophobic acrylic lenses with square-edge optics.<sup>15</sup>



### Comparison of preloaded IOLs

Company	Rayner	Alcon	Alcon	J&J
Lens platform	EMV	Acrysof IQ	Clareon	Tecnis1
Injector	RayOne	UltraSert	AutonoMe	іТес
Nd:YAG rate / PCO*	1.7% <sup>1</sup>	7.5% <sup>7</sup>	5.4% <sup>14</sup>	3.7%7
Miyata grade (glistenings)	0² (None)	1º (Glistenings)	015 (None)	0 <sup>12</sup> (None)
Abbe value	56²	379	Unknown	55°
Refractive index	1.46 <sup>3</sup>	1.55 <sup>10</sup>	1.55 <sup>12</sup>	1.4712
Mean decentration	0.08 mm⁴	0.78 mm <sup>11</sup>	0.06 mm <sup>13</sup>	0.27 mm <sup>13</sup>
Nozzle diameter	1.65 mm⁵	2.08 mm⁵	3.0 mm <sup>15</sup>	1.86 mm⁵
Injector preparation steps	2°	310	315	4 <sup>12</sup>

TABLE REFERENCES: 1. Mathew RG and Coombes AGA. Ophthalmic Surg Lasers Imaging. 2010 Nov-Dec; 41(6):651-5. 2. Rayner. Data on File. White paper. 3. Ferreira T et al. J of Refract Surg. 2019; 35(7): 418-25 4. Bhogal-Bhamra GK et al. Journal of Refractive Surgery. 2019;35(1):48-53. 5. Nanavaty MA and Kubrak-Kisza M. J Cataract Refract Surg 2017; 43:558-563. 6. www.rayner.com. 7. Cullin F et al. Acto Ophthalmol. 2014; 92(2): 179-83. 8. Yildirim TM et al. PLoS ONE. 2021; 16(4): e0250860. 9. Zhao H et al. Br J Ophthalmol. 2007; 91(9): 1225-29. 10. www.myalcon.com. 11. Humbert G et al. FX J Ophthalmol. 2013; 93(4): 352-61. 2. jinjvisionpro.com. 13. Baumeister M et al. J of Refract Surg. 2009; 35(6): 1006-12. 14. FDA Summary of Safety and Effectiveness Data PMA P190018 (2020). 15. Clareon IOL: A New Monofocal Platform. The Ophthalmologist. 2017.

\*Follow-up: RayOne=YAG at 24mths, Acrysof IQ=YAG at 41.4mths, Clareon=PCO at 12mths, Tecnis1=YAG at 41.5mths.

capsule contraction

### **RayOne injector**



#### **TWO-STEP SYSTEM**

• Easy to use<sup>10</sup>

i. Minimal learning curve ii. Minimises error

- Efficient IOL delivery time<sup>10</sup> 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
  2.2 mm incision
- Small fully preloaded injector nozzle
- i. Ease of insertion
- ii. Enables true micro incision
- Parallel sided for minimal stretch
- i. 2.2 mm delivery
- ii. Maintains incision architecture
- Ergonomic design for ease of handling
- 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. Minimises chance of contamination

### Lock & Roll technology



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

### In a comparative study of six market-leading preloaded delivery systems<sup>10</sup>

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





Ultrasert (U) (Alcon Laboratories, Inc.), iTec (iT) (Abbott Medical Optics, Inc.), Eyecee (E) (Bausch & Lomb, Inc.), iSert (iS) (Hoya Surgical Optics, Inc.), and CT Lucia (CT) (Carl Zeiss Meditec AG). All trademarks are property of their respective owners

RAYONE FULLY PRELOADED INJECTOR SYSTEM:





# RayPR@<sup>+</sup>

RAYPRO+ &

REFERENCES

### Real-time patient feedback data

RayPRO+ is a mobile and web-based digital platform that collects insightful Patient Reported Outcomes (PROs) over three years.

• New insightful trends

- Promote your services to new patients, with easy-to-understand metrics.
- Supports appraisals, recertification and auditing.
- Fast and simple
- Patients are registered in seconds.
- Only value-adding data is collected.
- Access metrics anytime from your smartphone (iOS and Android).

Google Play

- Automated collection of PROs
- Patients provide their feedback in just a couple of minutes.
- Responses are anonymous to encourage patient honesty.
- Reports are always live, with no data analysis needed.
- Use product and patient trends to improve your service.
- Secure cloud-based platform
- Designed for data security and to be GDPR and HIPAA compliant.
- Only you can see your personal RayPRO+ reports and metrics.
- Questionnaire responses are non-identifiable to protect patients' data privacy.

Download on the App Store RayPRO+ is FREE for users of Rayner IOLs. Subscription available for non-Rayner IOL users. Learn more at rayner.com/raypro



#### **RayOne EMV References:**

1. Ferreira TB. Comparison of visual outcomes of a monofocal, two enhanced monofocals and two extended depth of focus intraocular lenses. Presented at ESCRS 2022. 2. RayOne EMV: First Clinical Results, Rayner. Oct 2020. 3. Rayner RayPRO, data on file. 4. Rayner, data on file. 5. Rayner Peer2Peer webinar. May 2022. 6. Royo, M. RayOne EMV and TECNIS Eyhance: A Comparative Clinical Defocus Curve. Data on file. 2021. 7. How to Choose the Right Solution for Your Patients, CRSTE April 2021. 8. Bhogal-Bhamra GK, Sheppard AL, Kolli S, Wolffsohn JS. J Refract Surg. 2019;35(1):48-53. 9. Rayner. Data on File (RDTR 1937). 10. Nanavaty MA and Kubrak-Kisza M. J Cataract Refract Surg 2017; 43:558-563. 11. Rayner, PMCF data on file. 12. McLone E, Mahon G, Archer D, Best R. Br J Ophthalmol. 2001; 85:543-545. 13. Tomlins PJ, Sivaraj RR, Rauz S, Denniston AK, Murray PI. J Cataract Refract Surg. 2014; 40:618-625. 14. Rayner, data on file. 15. Mathew RG, Coombes AGA. Ophthalmic Surg Lasers Imaging. 2010 Nov-Dec; 41(6):651-5. 16. Vyas AV, Narendran R, Bacon PJ, Apple DJ. J Cataract Refract Surg 2007: 331-87 2007; 33:81-87.

## **Technical information**

Model Name	RayOne EMV	RayOne EMV Toric			
Model Number	RAO200E	RAO210T			
Power Range	+10.0 to +30.0 D (0.5 D increments)	SE: +10.0 D to +25.0 D (0.5 D increments) Cylinder: +0.75 D, +1.5 D, +2.25 D, +3.0 D, +3.75 D, +4.5 D			
Delivery System Type	Fully preloaded IOL injection system	·			
Incision Size	2.2 mm				
Delivery System					
Injector Type	Single use, fully preloaded IOL injection sys	stem			
Nozzle Size	1.65 mm				
Bevel Angle	/el Angle 45°				
Lens Delivery	Single handed plunger				
Aspheric Monofocal IOL					
Material	Single piece Rayacryl hydrophilic acrylic				
Water Content   26% in equilibrium					
UV Protection	Benzophenone UV absorbing agent	orbing agent			
UV Light Transmission					
Refractive Index	1.46				
ABBE	56				
Overall Diameter	12.50 mm				
Optic Diameter	6.00 mm				
Optic Shape	Biconvex (positive powers)				
Asphericity	Aspheric anterior surface				
Optic Edge Design Amon-Apple 360° enhanced square edge					
Haptic Angulation	ngulation 0°, uniplanar				
Haptic Style	Closed loop with anti-vaulting haptic (AVH) technology				

Estimated Constants for Optical Biometry									
	SRK/T	Haigis			HofferQ	Holladay	Holladay II	Barrett Universal II	
	A-constant	aO	a1	a2	pACD	SF	pACD	LF	DF
EMV	118.6	1.17	0.40	0.10	5.32	1.56	5.32	1.67	0
EMV 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.

### Join the conversation

Leading surgeons from around the world share their real-world experience with RayOne EMV - watch engaging webinars, listen to insightful interviews and podcasts, and read interesting case study articles.

Visit www.rayner.com/peer2peer to access videos and articles, download resources and join future events and discussions.





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