

# An enhanced monofocal IOL delivering >1.5D of high quality natural vision

Developed in collaboration with world renowned surgeon, Professor Graham Barrett, RayOne EMV is a highly versatile lens that meets the visual needs of a large population of cataract and refractive patients<sup>3</sup> looking for greater spectacle independence than offered by standard monofocal lenses.

#### RayOne EMV and RayOne EMV Toric offers:



Increased range of focus:  $1.5 \, D^{1,4,6}$  with an emmetropic target.



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



**Optimised for monovision:** Positive spherical aberration design and the resulting hyperopic tail provides a more natural range of vision with a smoother transition between distance and near eyes.<sup>2,4</sup>



**Easy to integrate:** A similar surgeon experience to your monofocal IOLs,<sup>5</sup> and now available on the RayOne Toric Platform.



"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"

# 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 is the only patented aspheric IOL 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 over 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).

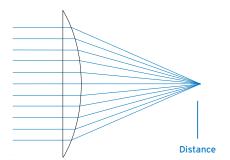


Figure 1 Standard monofocal IOL with zero spherical aberration

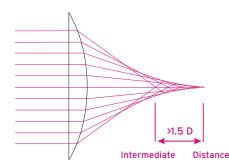


Figure 2 RayOne EMV with positive spherical aberration

Expected vision with a standard monofocal IOL



Expected vision with RayOne EMV



#### Why is positive spherical aberration good for extending depth of focus? 4

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.

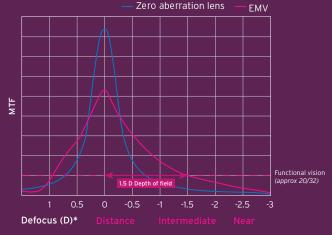


Figure 3

## Clinical results with RayOne EMV

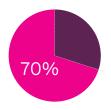
#### Since the launch of RayOne EMV in 2020, clinical data from across Europe has demonstrated that:1,2,3,6,7

- 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.

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
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
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



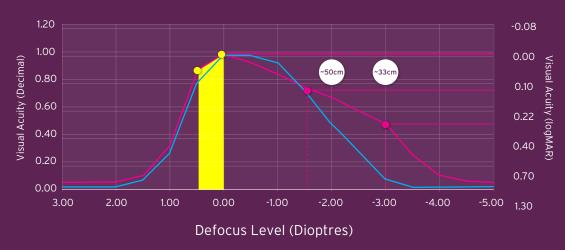
of patients reported no incidence of halo, glare, starbursts or haze



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>

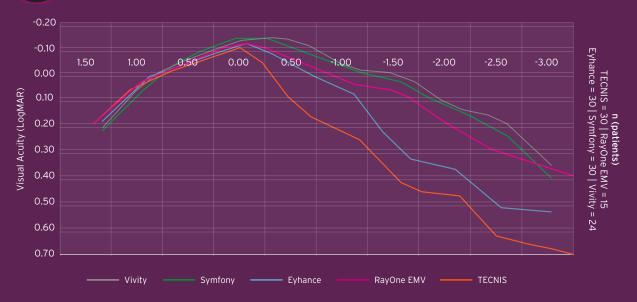


RayOne EMV — TECNIS Eyhance





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>







"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>

Binocular UDVA LogMAR	Cumulative %		
-0.1	41.70%		
0	100%		

n=24 eyes

Mean Binocular UDVA (LogMAR) -0.04 ±0.05

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

Binocular UIVA	Cumulative %		
N6	70%		
N8	100%		

n=20 eyes

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

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

n=20 eyes







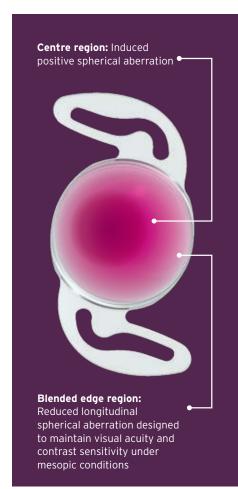


- >1.5 D increased range of focus with an emmetropic target.<sup>1,4,6</sup>
- Low levels of contrast sensitivity<sup>1</sup> and dysphotopsia<sup>2</sup>, similar to standard monofocal lenses.
- Positive spherical aberration design provides a natural range of vision.<sup>2,4</sup>

#### **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.





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

- Proven rotational stability and centration<sup>8</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



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

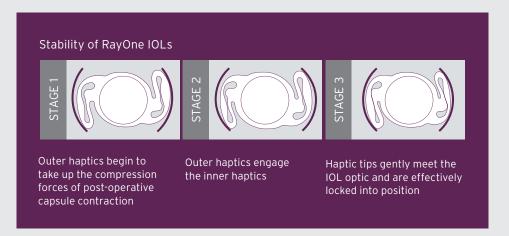
- Single piece IOL created from a homogeneous material free of microvacuoles<sup>9</sup>
- Compressible material for delivery through a 2.2 mm micro incision<sup>10</sup>
- Excellent handling characteristics with controlled unfolding within the capsular bag<sup>11</sup>
- Low silicone oil adherence<sup>12</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. 15,16

ND: YAG CAPSULOTO	DMY RATES <sup>7</sup>	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	200E	Acrysof IQ	Clareon	Tecnis1	
Injector	RayOne	UltraSert	AutonoMe	iTec	
Nd:YAG rate / PCO*	1.7%¹	7.5% <sup>7</sup>	5.4% <sup>14</sup>	3.7% <sup>7</sup>	
Miyata grade (glistenings)	O² (None)	18 (Glistenings)	O¹5 (None)	O <sup>12</sup> (None)	
Abbe value	56²	37 <sup>9</sup>	Unknown	55 <sup>9</sup>	
Refractive index	1.46³	1.55 <sup>10</sup>	1.55 <sup>12</sup>	1.47 <sup>12</sup>	
Mean decentration	0.08 mm <sup>4</sup>	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	<b>2</b> <sup>6</sup>	310	3 <sup>15</sup>	<b>4</b> <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. Acta 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. FR J Ophthalmol. 2013; 36(4): 352-61. 12. jnjvisionpro.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.

## RayOne injector



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

- Easy to use10
- i. Minimal learning curve
- ii. Minimises error
- Efficient IOL delivery time10
- 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. Fnables 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

# technology for consistent delivery

#### Lock & Roll technology







#### 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:

OVD priming

Advancing OVD in the nozzle

Nozzle insertion into the wound

IOL delivery

- 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 inserted through a 2.2 mm incision



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: THE QUEEN'S AWARDS FOR ENTERPRISE: INNOVATION 2020



#### Real-time patient feedback data

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

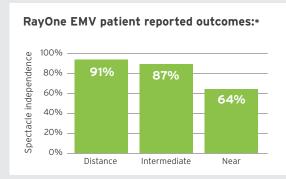
- New insightful trends
- Promote your services to new patients, with easy-to-understand metrics.
- Supports appraisals, recertification and auditing.
- Fast and simple
- Patients are registered in seconds.
- Only value-adding data is collected.
- Access metrics anytime from your smartphone (iOS and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

- 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.





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



\*RayPRO Patient Reported Metrics, 19 August 2022

# BESIDES STEEL THE WITH THE STEEL THE

#### RayOne EMV References:

1. Ferreira T. et al. Clinical outcomes comparison EMV vs. Eyhance, Symfony, Vivity. Presented at Winter 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. McLoone E, Mahon G, Archer D, Best R. Br J Ophthalmol. 2001; 85:543-545. 13. Tomlins PJ, Sivaraj RR, Rauz S, Denniston AK, Murray Pl. 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; 33:81-87.

Dysphotopsia:

0%

Night-time

## 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	45°	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					
UV Light Transmission	UV 10% cut-off is 380 nm					
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	O°, uniplanar					

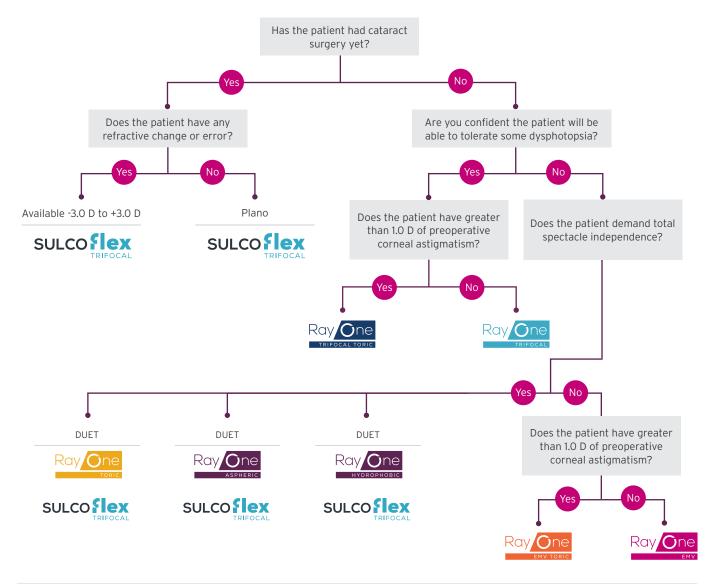
Estimated Constants for Optical Biometry									
	SRK/T	Haigis		HofferQ	Holladay	Holladay II	Barrett Universal II		
	A-constant	a0	a1	a2	pACD	SF	pACD	LF	DF
EMV	118.6	1.17	0.40	0.10	5.32	1.56	5.32	1.67	0
EMV Toric	118.6	1.044	0.40	0.10	5.32	1.56	5.32	1.67	3.5

Closed loop with anti-vaulting haptic (AVH) technology

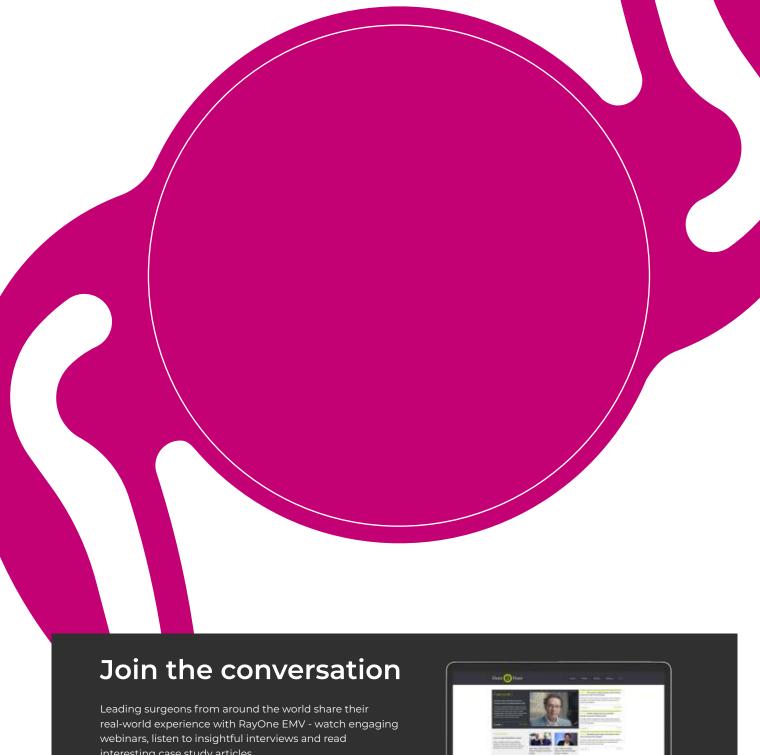
For Contact Ultrasound, the estimated A-constant is 118.0

Haptic Style

# Choosing the right lens for your premium patients



# One injector for all RayOne IOLs A single fully preloaded and repeatable injector for all RayOne IOLs reduces training for clinic teams and supports surgeon confidence in the operating room.



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