Vivinex™ multiSert™

CLARITY. CONTROL. COMBINED.

Vivinex™ offers **clarity of vision**
Delivered by **multiSert™**, providing
unmatched control at your fingertips

HOYA
SURGICAL OPTICS

Vivinex™ multiSert™

Designed to provide outstanding optical quality, Vivinex™ offers clarity of vision for patients suffering from cataract. Product quality, dedication and attention to detail are deeply rooted in our Japanese heritage...

... and with 2 million lenses implanted worldwide, surgeons' trust in Vivinex™ is proven.

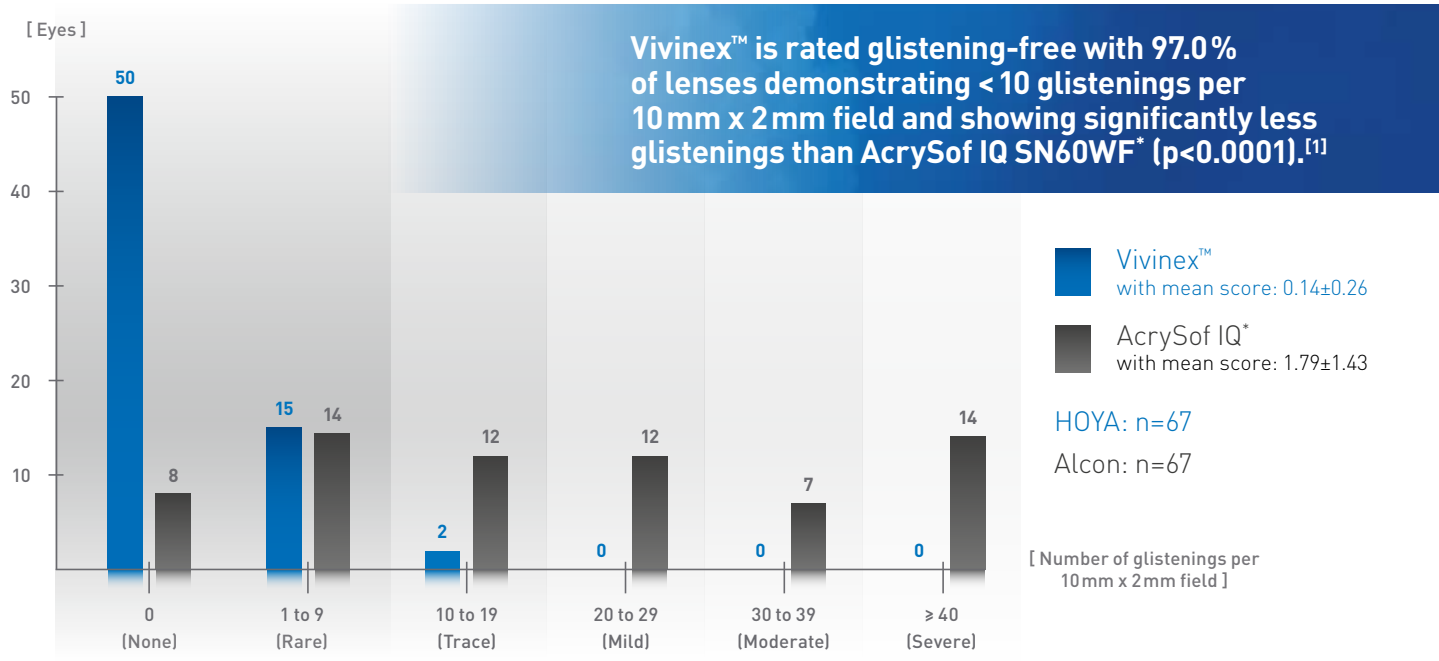
More than **2,000,000** Vivinex™ IOLs implanted

Hydrophobic acrylic Vivinex™ with UV-filter (Model XC1-SP), with UV- and blue light filter (Model XY1-SP)

Glistening-free hydrophobic IOL material

A randomised clinical study was conducted to independently compare Vivinex™ (Model XY1) with Alcon AcrySof IQ SN60WF*. Final results show glistening formation after 3-years post-op.[1]

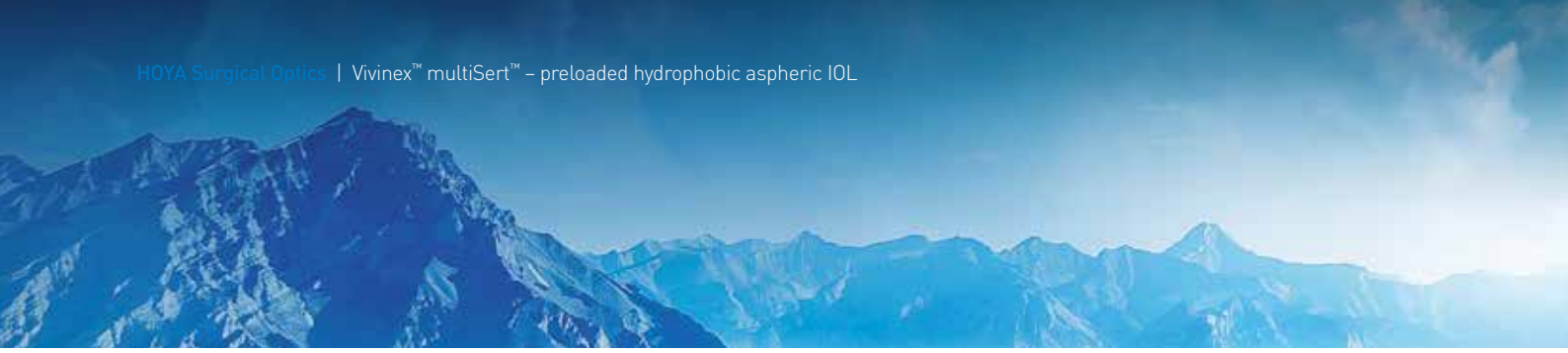
Clinical comparison of glistenings[2]



In vitro glistening formation at 14x magnification[3]

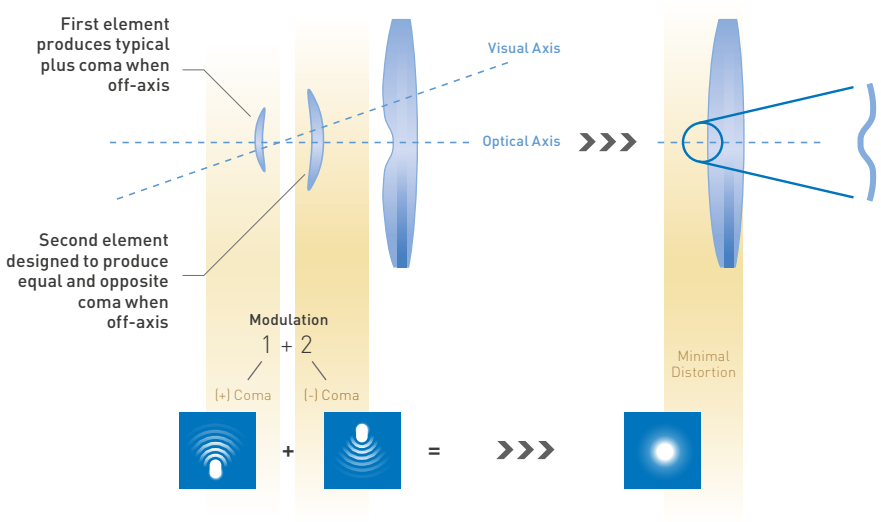
Vivinex™ XY1 (HOYA)
Grade 0 (glistening-free),
based on Miyata et al.[4]
with 11.6 ± 5.7 MV/mm²

AcrySof IQ SN60WF (Alcon)*
Grade 2-3,
based on Miyata et al.[4]
with 264.4 ± 110.3 MV/mm²



Proprietary aspheric optic design for improved image quality

HOYA's optic contains two distinct aspheric elements that are tuned to avoid typical induction of coma associated with traditional aspheric optics. These optical zones in the Vivinex™ IOL induce positive and negative coma to compensate for the loss of image quality caused by the natural misalignment between visual and optical axis in the eye.
The optic as a whole is designed to cancel out coma, providing patients with improved off-axis image quality versus traditional negative aspheric IOL designs.[5]



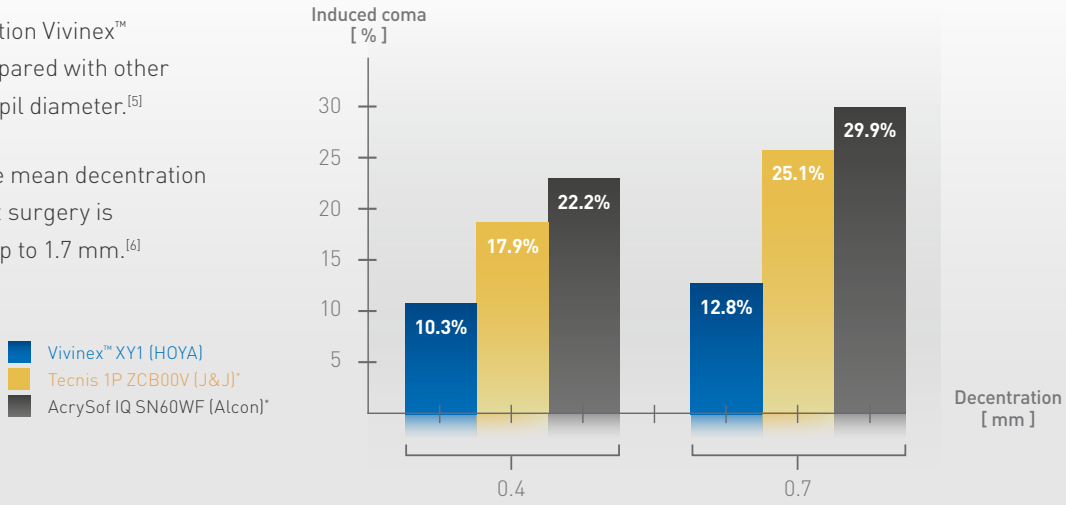
The proprietary aspheric optics of Vivinex™ reduce spherical aberration without incurring significant susceptibility to decentration-associated coma.[5]

This image is for illustrative purposes only and may not be an exact representation of the product.

Reduced coma caused by off-axis alignment

In the presence of decentration Vivinex™ minimises coma when compared with other aspheric IOLs at 4.0 mm pupil diameter.[5]

Studies have shown that the mean decentration of an IOL following cataract surgery is 0.4 ± 0.2 mm with a range up to 1.7 mm.[6]



Active oxygen processing treatment, a smooth surface and square optic edge to reduce PCO

Vivinex™ is made from a novel hydrophobic acrylic, using a proprietary manufacturing process that includes a unique, active oxygen posterior surface treatment. This as well as its square edge design and one of the smoothest and most regular IOL surfaces has been shown to provide a low incidence of PCO in several studies.[1,7,8,9,10,11,12,13]

Reduction of PCO

	Vivinex™ XY1 (HOYA)		AcrySof IQ SN60WF (Alcon)*	
Objective (EPCO score)	0.12 ± 0.19	n = 57	0.24 ± 0.46	n = 57
Subjective (slit lamp score)	0.30 ± 0.55	n = 67	0.48 ± 0.84	n = 67
Nd:YAG rate	0.0%	n = 67	1.5%	n = 67

P = .026 | P = .044 | P = 1.00

In a randomized multi-center trial, Vivinex™ demonstrated significantly lower objective and subjective PCO scores versus AcrySof IQ* after 3-years.[1]

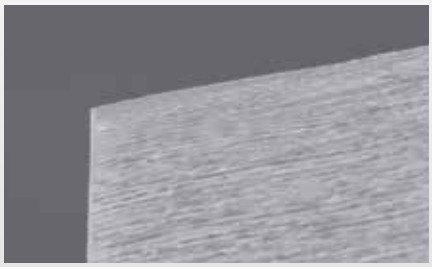
Objective (AQUA score)	0.9 ± 0.8	n = 64	1.4 ± 1.1	n = 62
Subjective (slit lamp score)	1.4 ± 1.4	n = 64	2.3 ± 2.0	n = 62
Nd:YAG rate	11.4%	n = 70	18.6%	n = 70

P < .001 | P = .001 | P = .23

In a randomized single-center trial, Vivinex™ demonstrated significantly lower objective and subjective PCO scores compared to AcrySof IQ* after 3-years.[7]

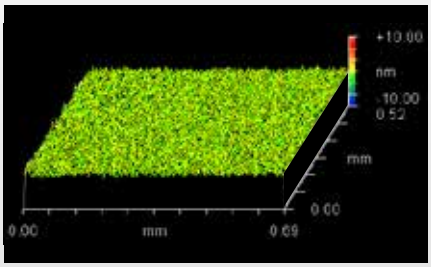
These results confirm low occurrence of PCO in both IOL groups and significantly lower PCO incidence with Vivinex™ compared to AcrySof IQ*.

The posterior edge profile of Vivinex™ has a radius of curvature of <10.0 µm providing a mechanical barrier against LEC migration.[1,7,12,13]



Scanning electron microscope (SEM) image of the posterior Vivinex™ edge at 1500x magnification

The Vivinex™ hydrophobic acrylic IOL material has one of the smoothest and most regular surfaces, which is associated with reduced PCO.[8,9]



Topographic image of the Vivinex™ IOL surface at 10x magnification

Delivery by multiSert™, providing unmatched control at your fingertips

With multiSert™, the 4-in-1 delivery system, HOYA has developed a preloaded injector that offers the surgeon two injection options within one device. Providing single-handed push and two-handed screw injection, multiSert™ is designed to meet the surgeons' requirements and supports their personal preferences.

Single-handed push and two-handed screw injection within one device

It's your Choice

Single-handed push injection

or

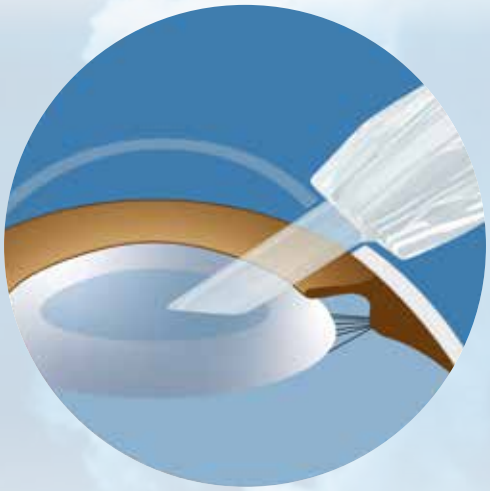
Two-handed screw injection

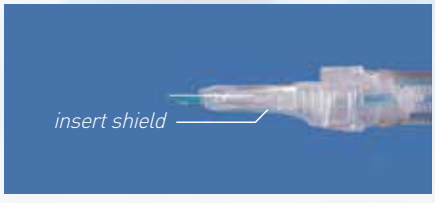
Uniquely designed adjustable *insert shield* for precise injector tip insertion depth management

The innovative multiSert™ *insert shield* provides additional assurance – surgeons can modulate the insertion depth according to preference, and therefore insert the injector tip **either directly into the capsular bag or through the incision wound tunnel:** no other IOL delivery system offers this feature.

It's your Choice

Delivery into capsular bag

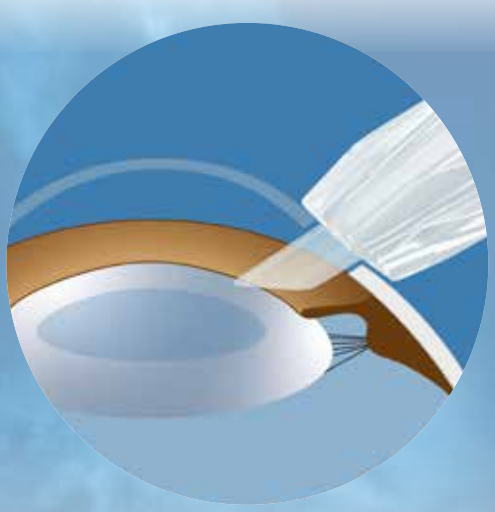


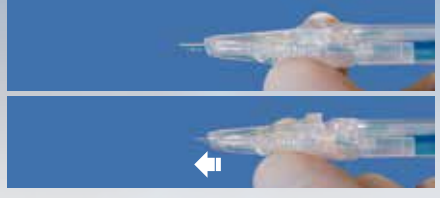


insert shield:
default position

or

Delivery through incision wound tunnel





insert shield:
advanced position

One fits all –
4-in-1 multiSert™ preloaded injector

multiSert™ provides outstandingly consistent and predictable IOL delivery

100 %

Of leading and trailing haptics were consistently tucked correctly [14]

0 %

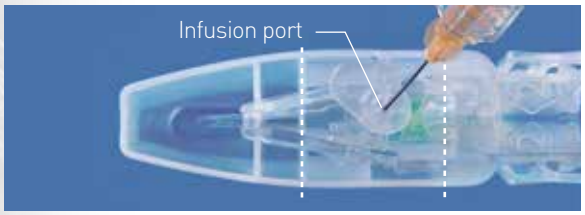
Complications or adverse events [14]

0 %

Broken injector tips after IOL release [14]

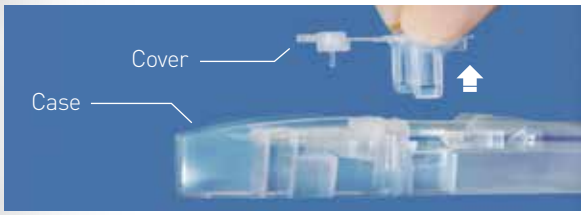
Usability and acceptability evaluation of multiSert™ was performed in the operating rooms of 14 European clinics (in Austria, France and Germany). 221 cases were completed in accordance with the instructions for use.[14]

Ready for implantation in four easy preparation steps



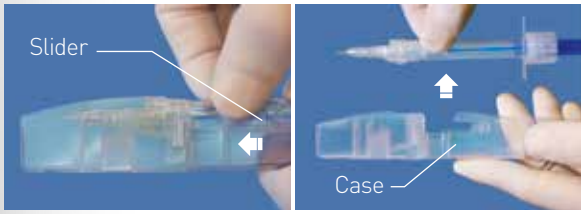
Step 1:

Infuse the sodium hyaluronate OVD into the injector through the infusion port.



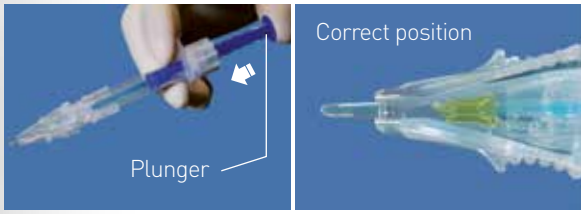
Step 2:

Press the release tabs, lift up and remove the cover from the injector case.



Step 3:

Hold injector body with thumb and slowly push the slider forward. Remove the injector from the case.

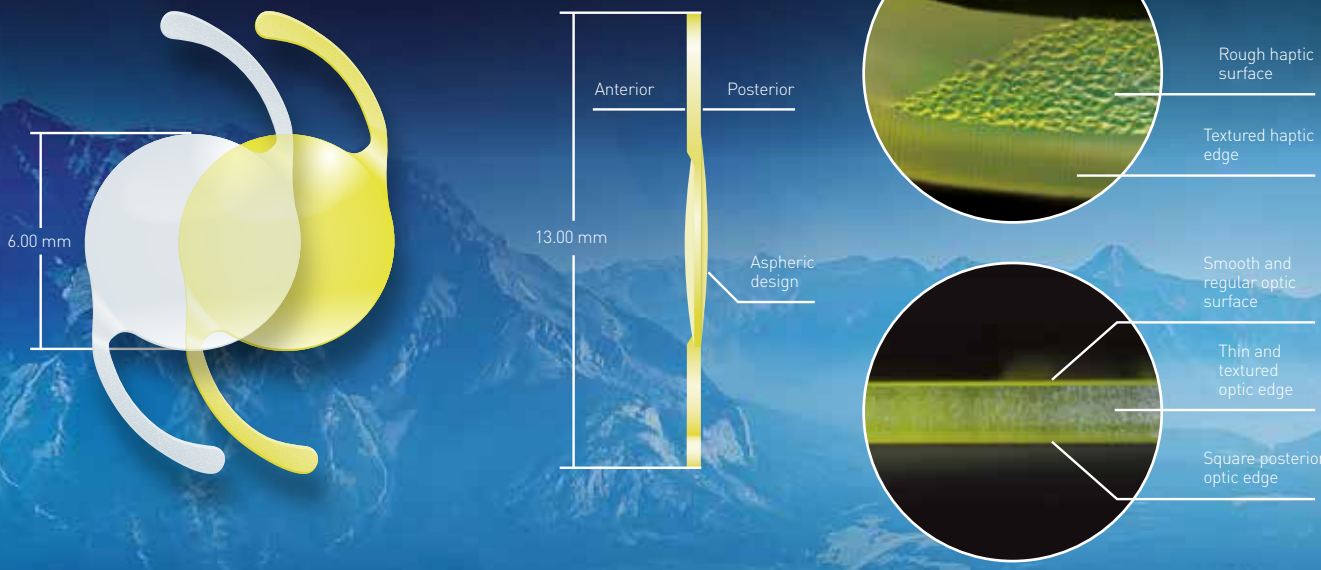


Step 4:

Gently advance the plunger forward and confirm that the leading and trailing haptic are tucked correctly.

The handling shown above illustrates in summary the product application and does not replace the Instruction For Use.

Technical characteristics



Vivinex™ multiSert™				
Model name	**XC1-SP | XY1-SP**			
Optic design	Aspheric design with square, thin and textured optic edge			
Optic & haptic materials	Hydrophobic acrylic Vivinex™ with UV-filter (Model XC1-SP), with UV- and blue light filter (Model XY1-SP)			
Haptic design	Textured-rough haptic surface			
Diameter (optic/OAL)	6.00 mm / 13.00 mm			
Power	+6.00 to +30.00 D (in 0.50 D increments)			
Nominal A-constant**	118.9			
Optimized constants***	Haigis	a_0 = -0.8028	a_1 = 0.2133	a_2 = 0.2245
	Hoffer Q	pACD = 5.697		
	Holladay 1	sf = 1.934		
	SRK/T	A = 119.198		
Injector	**multiSert**™ preloaded			
Front injector tip outer diameter	1.70 mm			
Recommended incision size	2.20 mm			

** The A-constant is presented as a starting point for the lens power calculation. When calculating the exact lens power, it is recommended that calculations be performed individually, based on the equipment used and operating surgeon's own experience.

*** These optimized constants for the calculation of intraocular lens power published by IOLCon on their website: https://iolcon.org are calculated from 1,475 clinical results for Vivinex™ model XY1/XC1 as of September 24, 2021. These constants are based on actual surgical data and are provided by IOLCon as a starting point for individual constant optimizations. The information available on the website is based on data originating from other users and not by HOYA Surgical Optics ("HSO"). HSO therefore does not warrant the correctness, completeness and currentness of the contents on the said website.

Vivinex™ multiSert™

CLARITY. CONTROL. COMBINED.

Vivinex™ offers clarity of vision

- **Glistening-free hydrophobic** acrylic IOL material [1,3]
- **Proprietary aspheric optic design** for improved image quality [5]
- **Active oxygen processing treatment**, a **smooth surface** and **square optic edge** to reduce PCO [1,7,8,9,10,11,12,13]

multiSert™ provides unmatched control at your fingertips

- **Single-handed push** and **two-handed screw injection** within one device
- **Uniquely designed adjustable *insert shield*** for precise injector tip insertion depth management
- **multiSert™** provides **outstandingly consistent** and **predictable IOL delivery** [14]

1 HOYA data on file. DoF-CTM-21-002, HOYA Medical Singapore Pte. Ltd, 2021

2 Christiansen, G.et al. (2001): Glistenings in the AcrySof intraocular lens: pilot study. In: Journal of cataract and refractive surgery 27 (5), p. 728–733.

3 Tandogan, T. et al. (2021): In-vitro glistening formation in six different foldable hydrophobic intraocular lenses. In BMC Ophthalmol 21, 126.

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8 Giacinto, C. et al. (2019): Surface properties of commercially available hydrophobic acrylic intraocular lenses: Comparative study. In: Journal of cataract and refractive surgery 45 (9), p. 1330–1334.

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10 Matsushima, H. et al. (2006): Active oxygen processing for acrylic intraocular lenses to prevent posterior capsule opacification. In: Journal of cataract and refractive surgery 32 (6), p. 1035–1040.

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13 Nanavaty, M. et al. (2019): Edge profile of commercially available square-edged intraocular lenses: Part 2. In: Journal of cataract and refractive surgery 45 (6), p. 847–853.

14 HOYA data on file. DoF-SERT-102-MULT-03052018, HOYA Medical Singapore Pte. Ltd, 2018

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