Vivinex™ multiSert™

CLARITY. CONTROL. COMBINED.

Vivinex™ IOL and the 4-in-1 multiSert™ preloaded injector system – A game changer in the delivery of high quality hydrophobic IOLs.

HOYA
SURGICAL OPTICS

Vivinex™ Unprecedented clarity of vision

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

... and with 1 million lenses sold worldwide, surgeons' trust in Vivinex™ is proven.

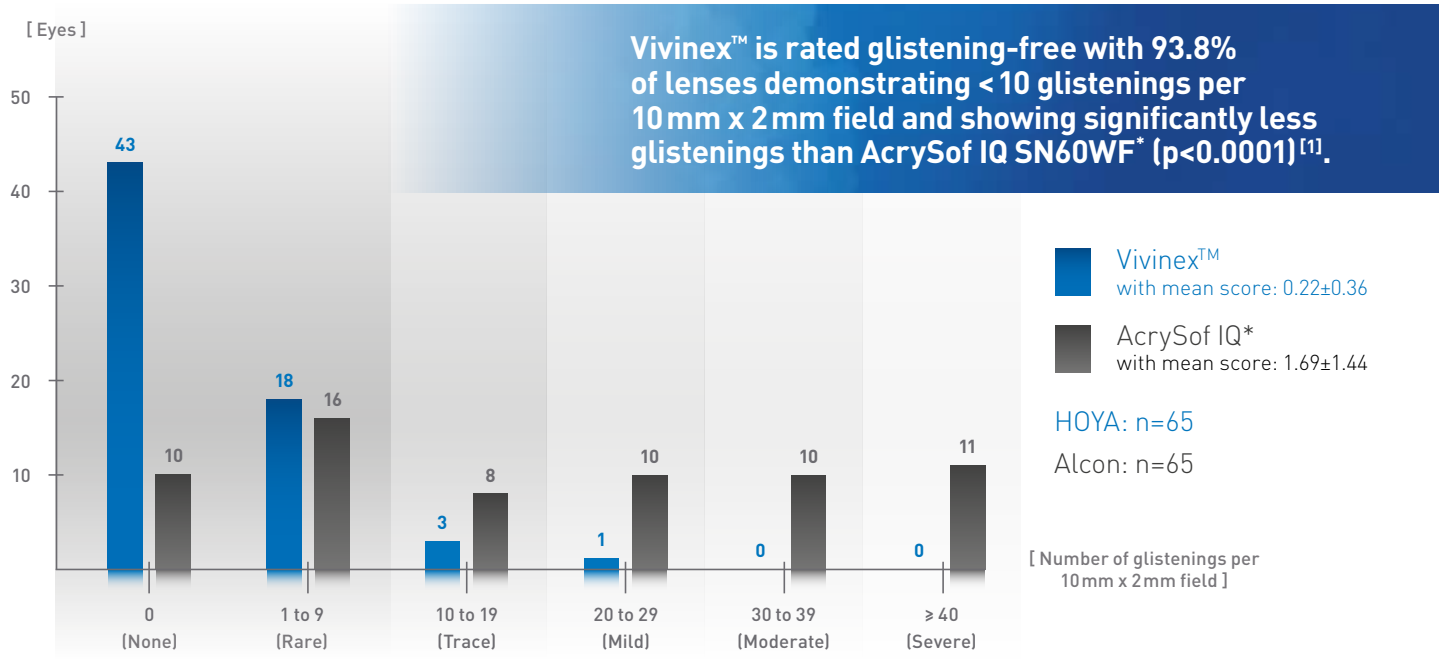
More than 1,000,000 Vivinex™ IOLs sold

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*. Interim results show glistening formation after 24-months post-op[1].

Clinical comparison of glistenings[2]



Vivinex™ is rated glistening-free with 93.8% of lenses demonstrating < 10 glistenings per 10 mm x 2 mm field and showing significantly less glistenings than AcrySof IQ SN60WF* (p<0.0001)[1].

Vivinex™
with mean score: 0.22±0.36

AcrySof IQ*
with mean score: 1.69±1.44

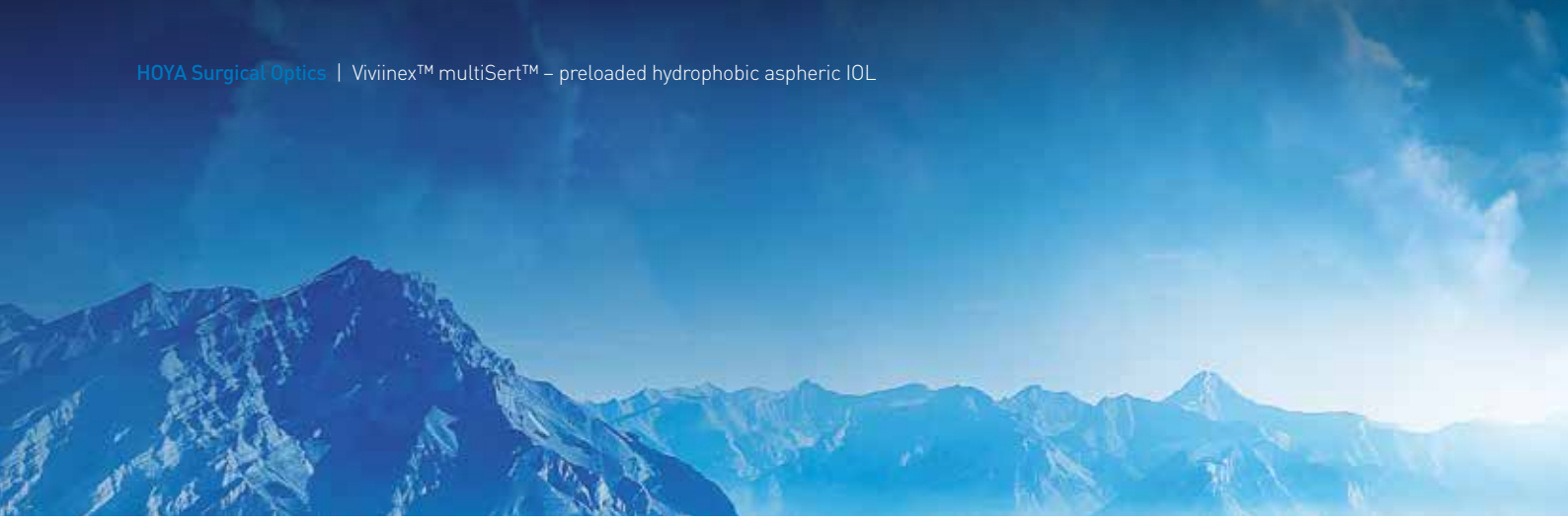
HOYA: n=65

Alcon: n=65

In vitro glistening formation at 14x magnification[3]

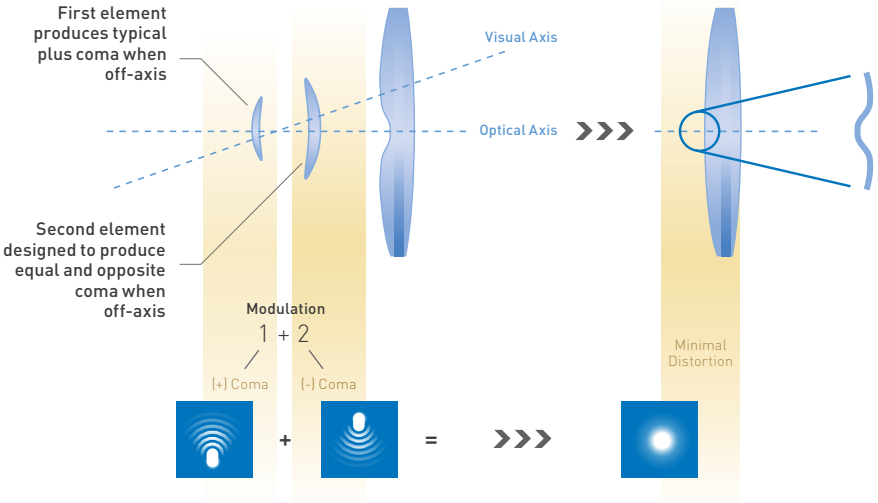
Vivinex™ XY1 (HOYA)
Grade 0 (glistening-free),
based on Miyata et al.[4]
with 11.6 ± 5.7 MV/mm²

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].

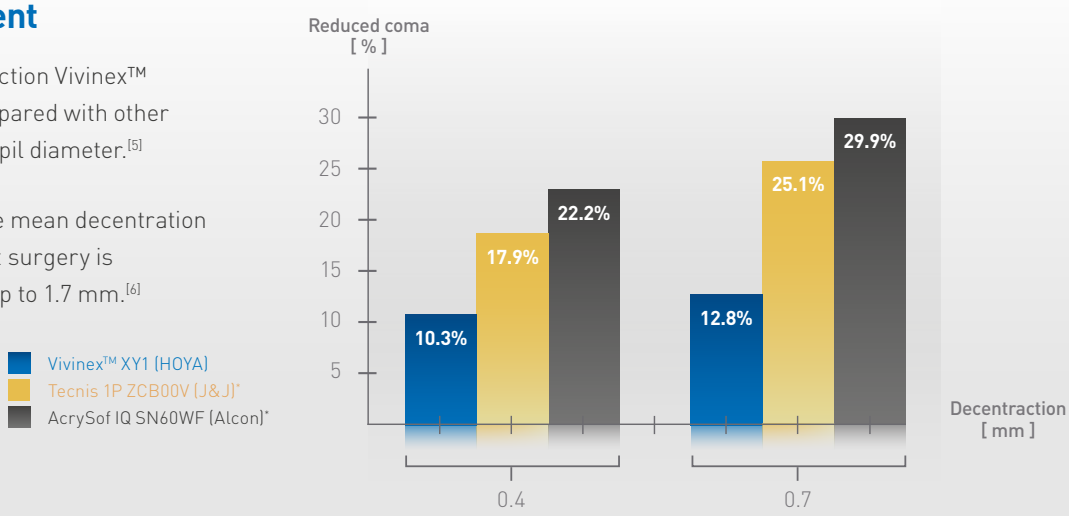


The proprietary aspheric optics of Vivinex™ reduce spherical aberration without incurring significant susceptibility to decentration-associated coma[5].

Reduced coma caused by off-axis alignment

In the presence of decentraction 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 and sharp optic edge to reduce PCO

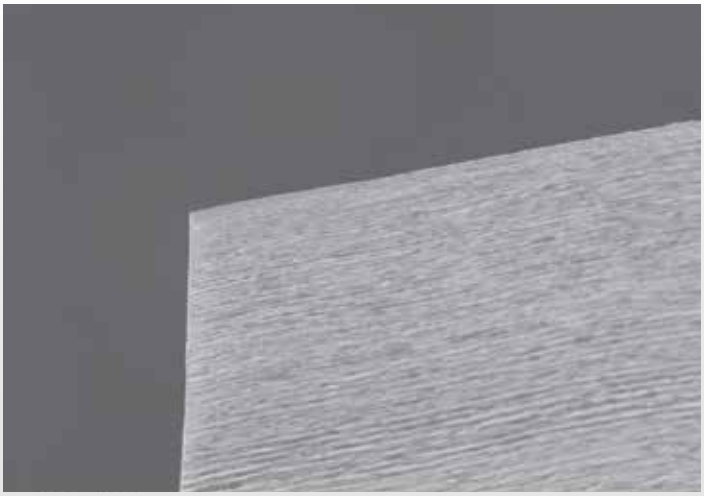
Vivinex™ is made from a novel hydrophobic acrylic, using a proprietary manufacturing process that includes a unique, active oxygen posterior surface treatment. This, and its sharp edge design lead to significantly reduced PCO-rates [1].

Unsurpassed reduction of PCO

Vivinex™ XY1 (HOYA)	AcrySof IQ SN60WF (Alcon)*
0,0%	1,5%
Nd:YAG Laser Capsulotomy rate	Nd:YAG Laser Capsulotomy rate
n=65	n=65

Vivinex™ shows a lower Nd:YAG Laser Capsulotomy rate at 24 months post-op in comparison to Alcon AcrySof IQ* [1].

Sharp optic edge of Vivinex™ is designed to mimimize PCO



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

multiSert™ Unmatched control at your finger tips

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

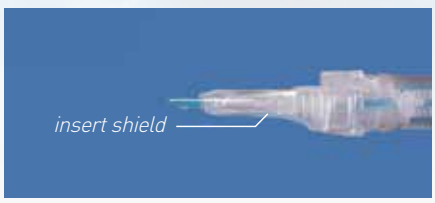
Two-handed screw injection

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.

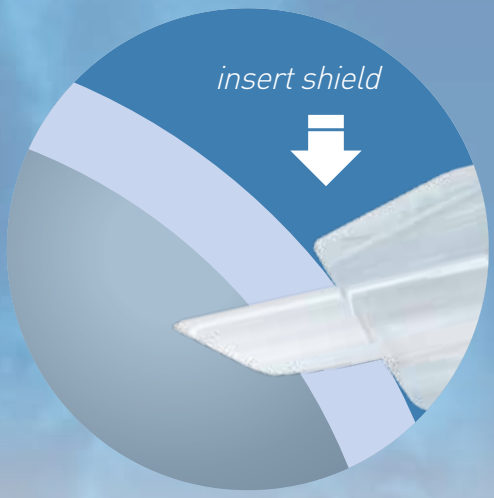
It's your Choice

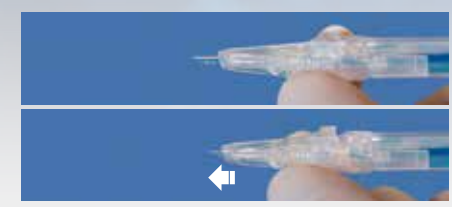
Delivery into capsular bag



or

Delivery through incision wound tunnel





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

Preloaded injector provides outstandingly consistent and predictable IOL delivery

100 %

Of leading and trailing haptics were consistently tucked correctly [7]

0 %

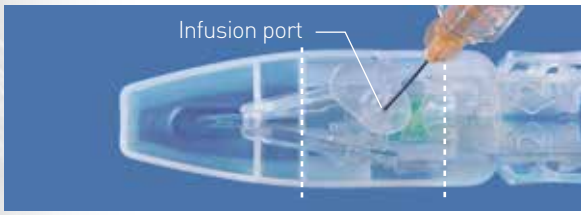
Complications or adverse events [7]

0 %

Broken injector tips after IOL release [7]

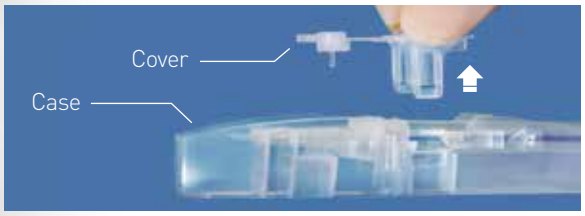
Usability and acceptability evaluation of multiSert™ was performed in the operating rooms of 14 European clinics (in Austria, France and Germany). 221 cases were completed in accordance with the instructions for use[7].

Ready for implantation in four easy preparation steps



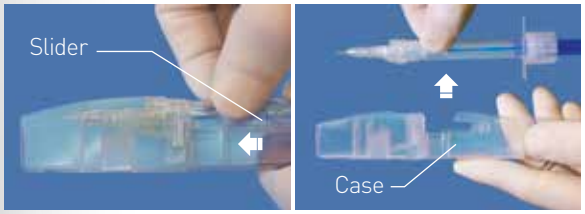
Step 1:

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



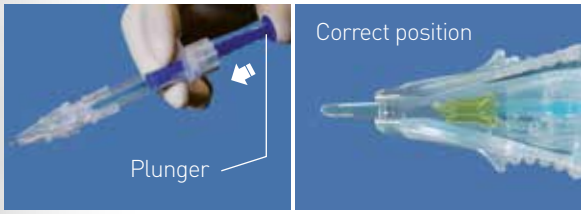
Step 2:

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.

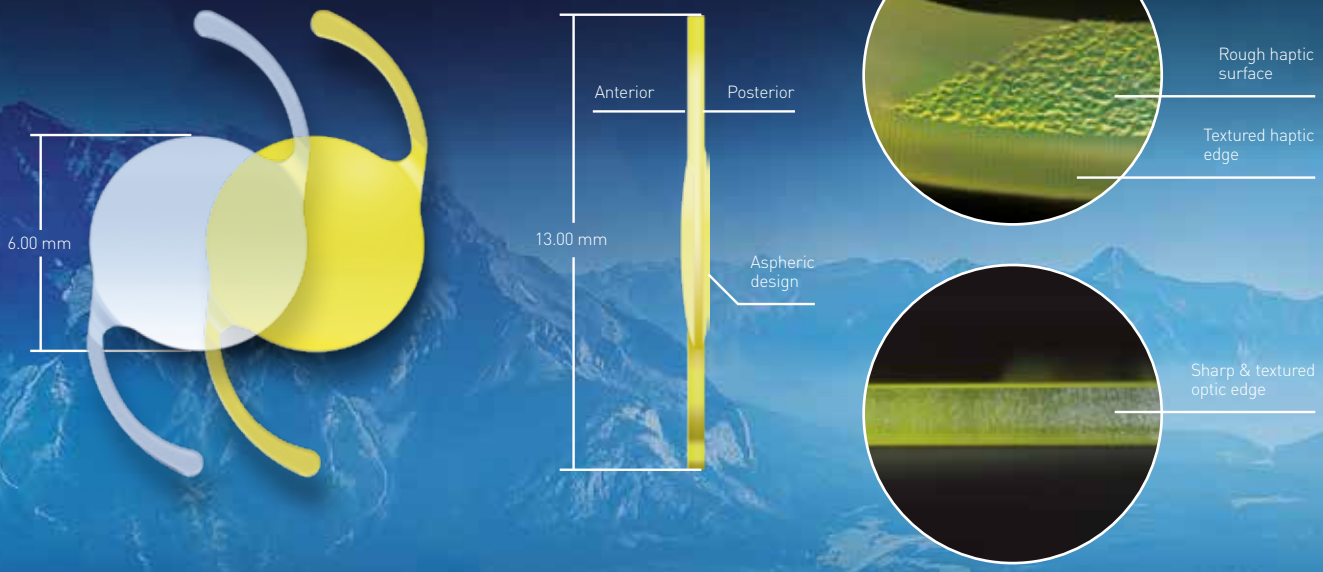


Step 4:

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 sharp 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 = -0.8394	a_1 = 0.2023	a_2 = 0.2272
	Hoffer Q	pACD = 5.7058		
	Holladay 1	sf = 1.9432		
	SRK/T	A = 119.219		
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.

*** Source: https://iolcon.org Calculated from 910 clinical results based on Caucasian patients as of August 22, 2019

Vivinex™ multiSert™

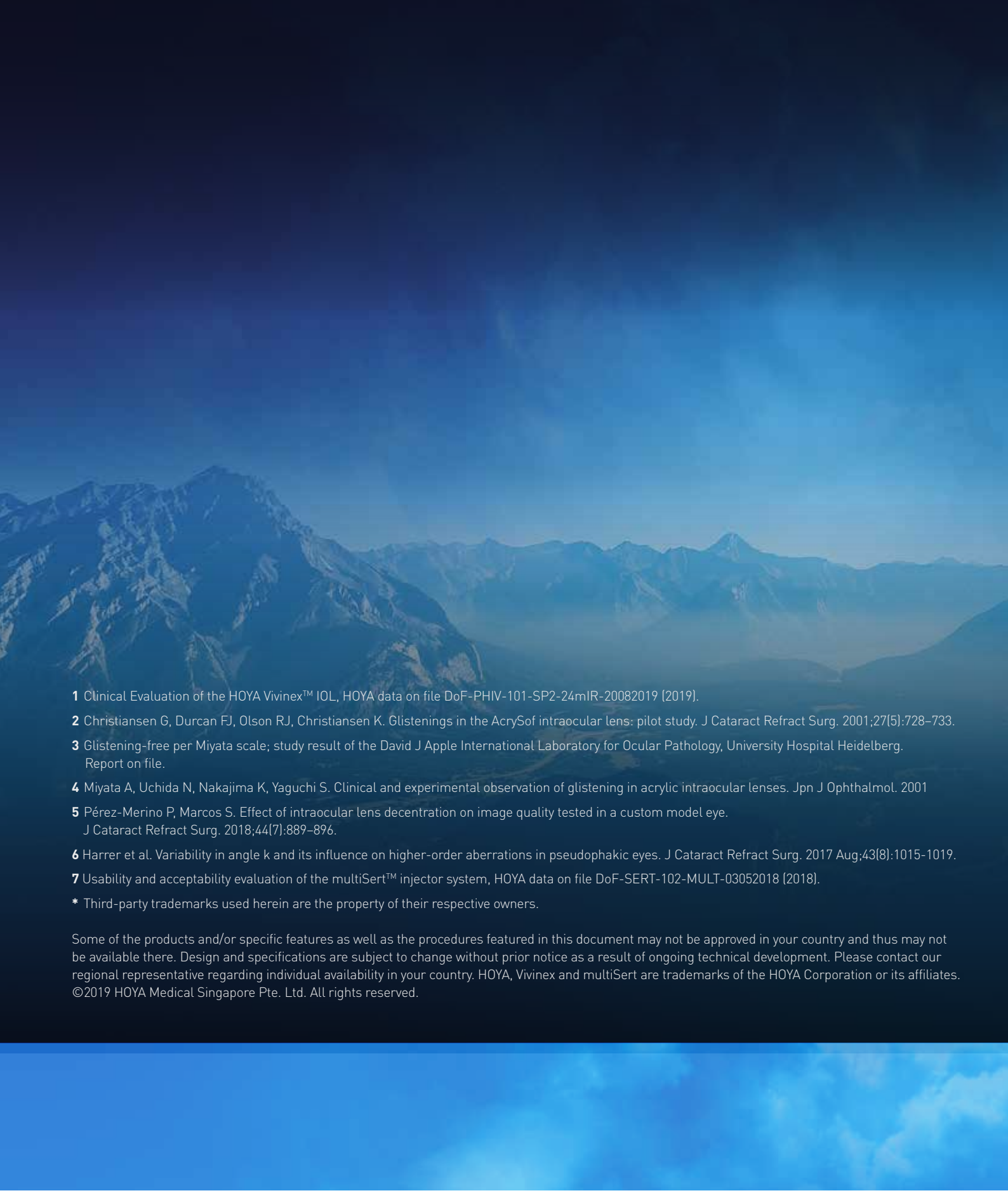
CLARITY. CONTROL. COMBINED.

Unprecedented clarity of vision

- Glistening-free **hydrophobic acrylic IOL material** [1,3]
- Proprietary **aspheric optic design** for improved image quality [5]
- **Active oxygen processing treatment** and **sharp optic edge to reduce PCO** [1]

Unmatched control at your finger tips

- **Single-handed push** and **two-handed screw injection** within one device
- **Uniquely designed adjustable *insert shield*** for precise injector tip insertion depth management
- **Preloaded injector provides outstandingly consistent** and **predictable IOL delivery** [7]



1 Clinical Evaluation of the HOYA Vivinex™ IOL, HOYA data on file DoF-PHIV-101-SP2-24mIR-20082019 (2019).

2 Christiansen G, Durcan FJ, Olson RJ, Christiansen K. Glistenings in the AcrySof intraocular lens: pilot study. J Cataract Refract Surg. 2001;27(5):728–733.

3 Glistening-free per Miyata scale; study result of the David J Apple International Laboratory for Ocular Pathology, University Hospital Heidelberg. Report on file.

4 Miyata A, Uchida N, Nakajima K, Yaguchi S. Clinical and experimental observation of glistening in acrylic intraocular lenses. Jpn J Ophthalmol. 2001

5 Pérez-Merino P, Marcos S. Effect of intraocular lens decentration on image quality tested in a custom model eye. J Cataract Refract Surg. 2018;44(7):889–896.

6 Harrer et al. Variability in angle k and its influence on higher-order aberrations in pseudophakic eyes. J Cataract Refract Surg. 2017 Aug;43(8):1015-1019.

7 Usability and acceptability evaluation of the multiSert™ injector system, HOYA data on file DoF-SERT-102-MULT-03052018 (2018).

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