Vivinex™ iSert®

VIVINEX™ OFFERS CLARITY OF VISION

Vivinex™ preloaded in the **Vivinex™ iSert®** injector
provides **outstanding delivery consistency**

HOYA
SURGICAL OPTICS

Vivinex™ iSert®

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.

- Glistening-free hydrophobic acrylic IOL material[1,2]
- Proprietary aspheric optic design for improved image quality[3]
- Active oxygen processing treatment, a smooth surface and square optic edge to reduce PCO[1,4,5,6,7,8,9,10]

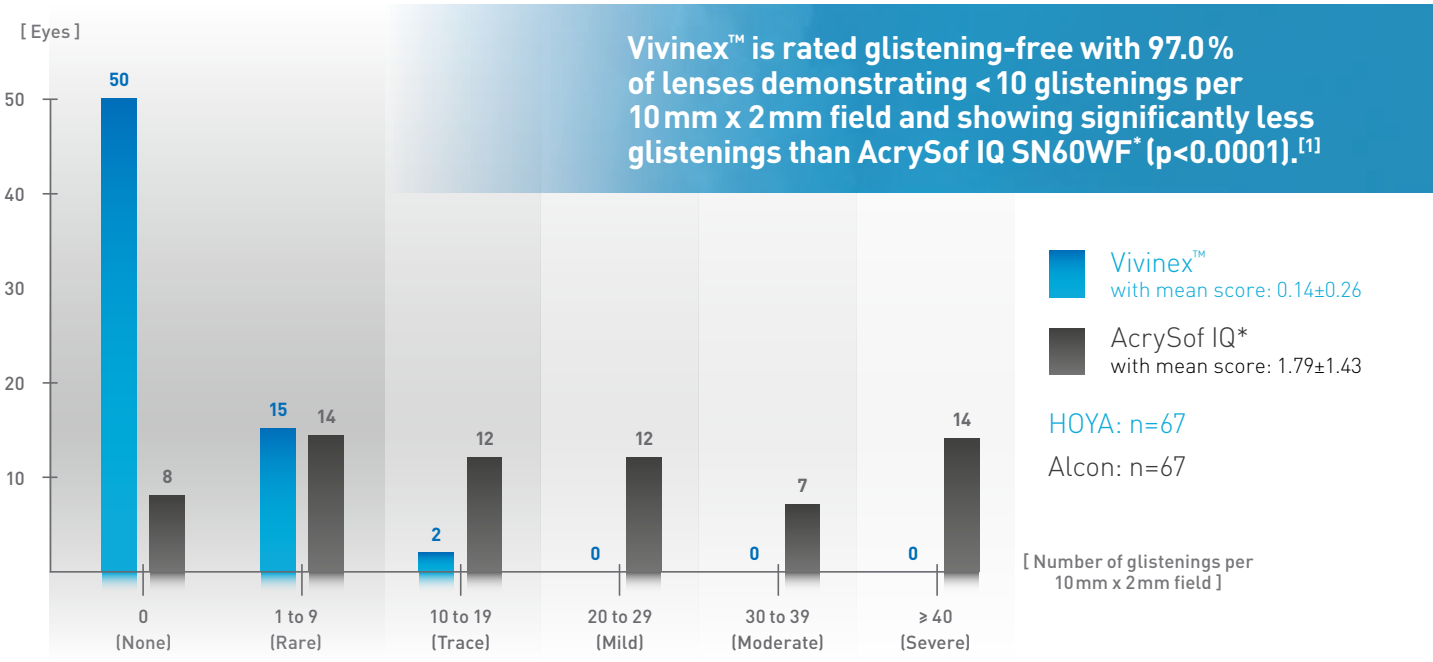
More than 2,000,000 Vivinex™ IOLs implanted

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

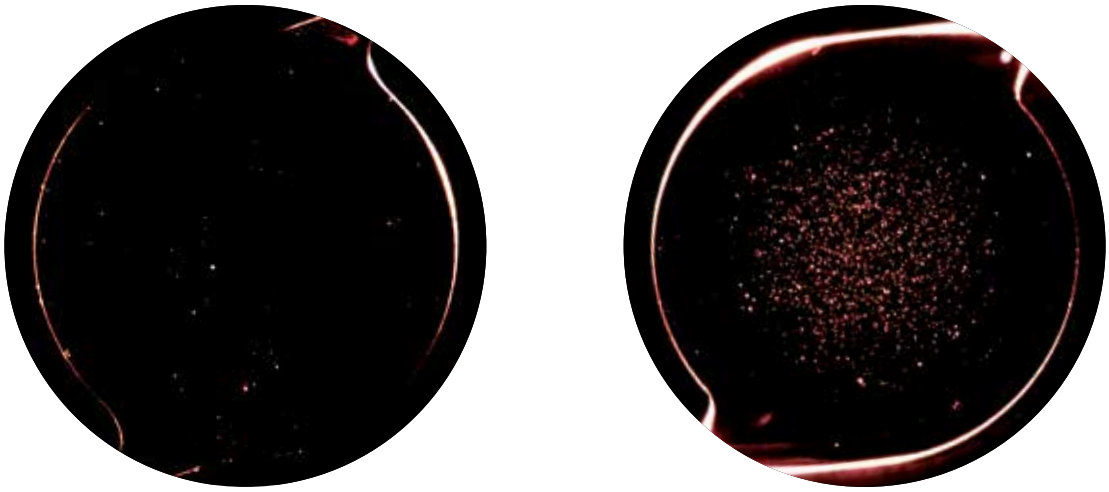
Glistening-free hydrophobic IOL material

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[11]



In vitro glistening formation at 14x magnification[2]

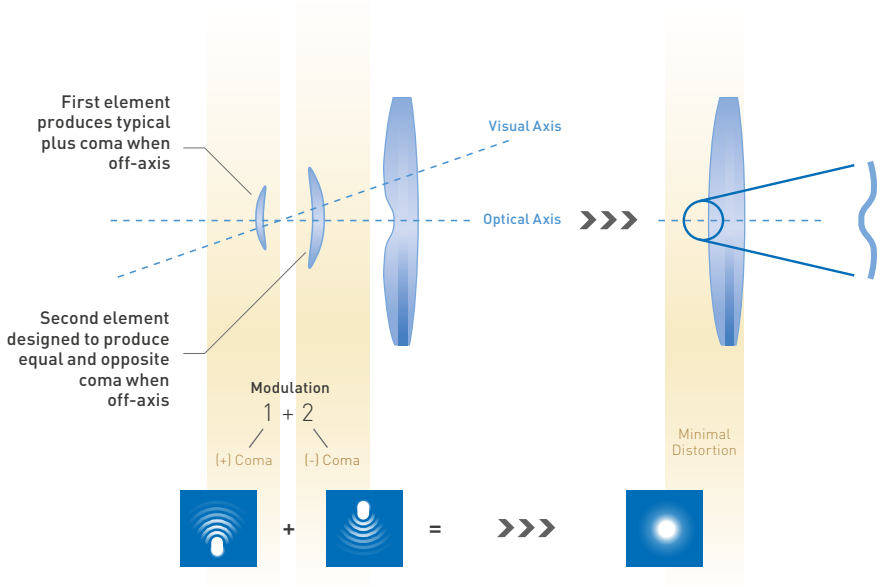


Vivinex™ XY1 (HOYA)
Grade 0 (glistening-free),
based on Miyata et al.[12]
with 11.6 ± 5.7 MV/mm²

AcrySof IQ SN60WF (Alcon)*
Grade 2-3,
based on Miyata et al.[12]
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.[3]



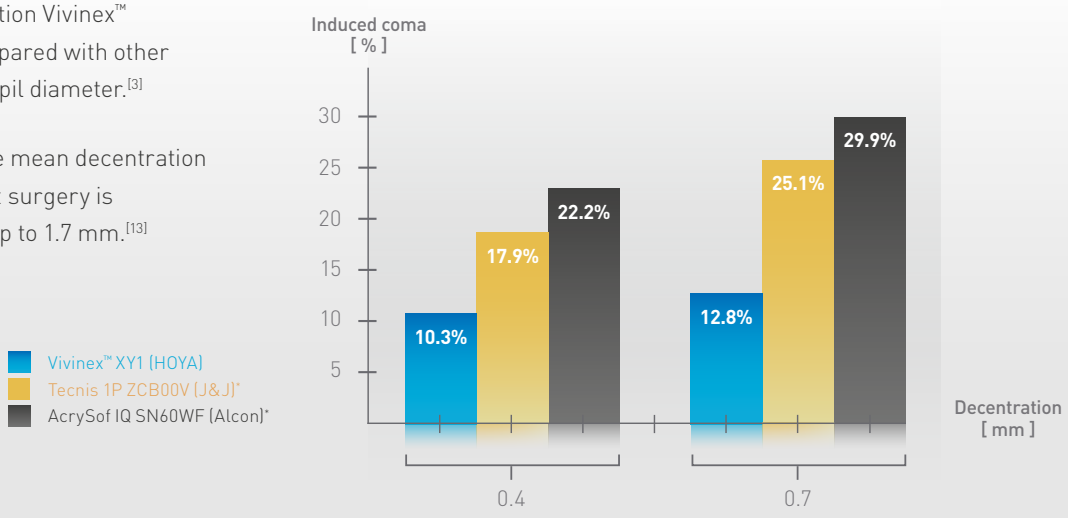
The proprietary aspheric optics of Vivinex™ reduce spherical aberration without incurring significant susceptibility to decentration-associated coma.[3]

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

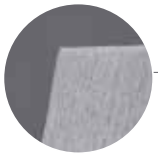
Reduced coma caused by off-axis alignment

In the presence of decentration Vivinex™ minimises coma when compared with other aspheric IOLs at 4.0 mm pupil diameter.[3]

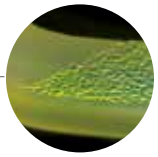
Studies have shown that the mean decentration of an IOL following cataract surgery is 0.4 ± 0.2 mm with a range up to 1.7 mm.[13]



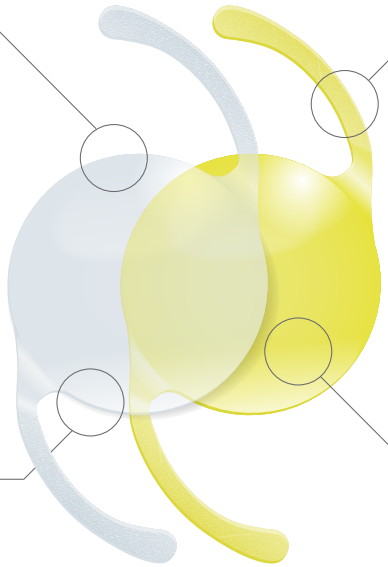
Vivinex™ IOL design



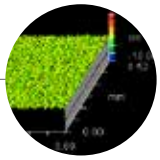
Square posterior optic edge
The posterior edge profile of Vivinex™ has a radius of curvature of <10.0µm providing a mechanical barrier against LEC migration.[5]



Textured-rough haptic
For better grip inside the capsular bag and designed to reduce the potential for adhesion to the optic surface.



Thin and textured optic edge
Designed to reduce reflections that may cause dysphotopsia.[14,15]



Smooth and regular optic surface
Associated with reduced PCO.[6,7]

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.[1,4,5,6,7,8,9,10]

Reduction of PCO

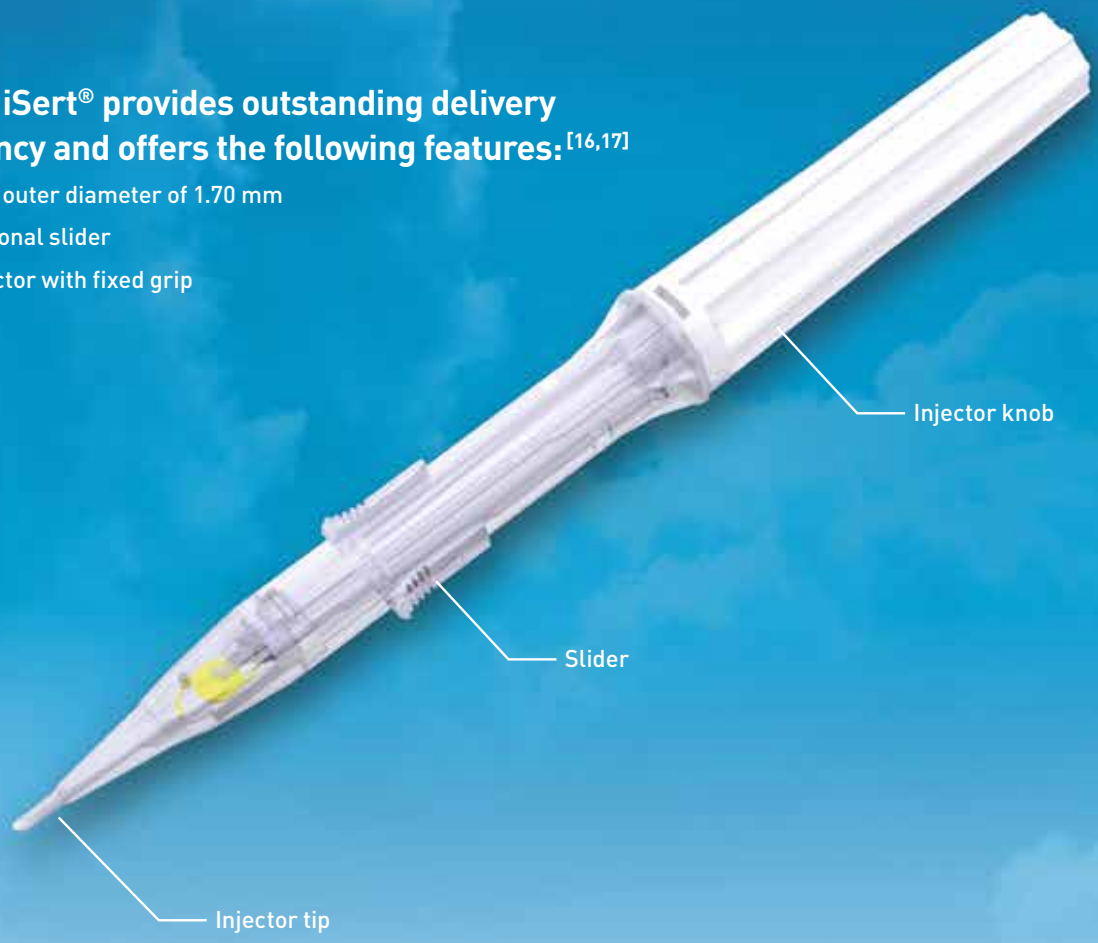
	Vivinex™ XY1 (HOYA)		AcrySof IQ SN60WF (Alcon)*	
Objective (EPCO score)	0.12 ± 0.19 n = 57	P = .026	0.24 ± 0.46 n = 57	In a randomized multi-center trial, Vivinex™ demonstrated significantly lower objective and subjective PCO scores versus AcrySof IQ* after 3-years.[1]
Subjective (slit lamp score)	0.30 ± 0.55 n = 67	P = .044	0.48 ± 0.84 n = 67	
Nd:YAG rate	0.0% n = 67	P = 1.00	1.5% n = 67	
Objective (AQUA score)	0.9 ± 0.8 n = 64	P < .001	1.4 ± 1.1 n = 62	In a randomized single-center trial, Vivinex™ demonstrated significantly lower objective and subjective PCO scores compared to AcrySof IQ* after 3-years.[4]
Subjective (slit lamp score)	1.4 ± 1.4 n = 64	P = .001	2.3 ± 2.0 n = 62	
Nd:YAG rate	11.4% n = 70	P = .23	18.6% n = 70	

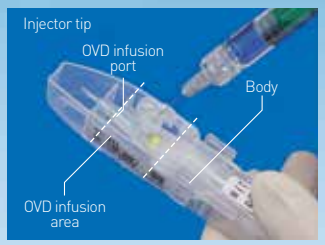
These results confirm low occurrence of PCO in both IOL groups and significantly lower PCO incidence with Vivinex™ compared to AcrySof IQ*.

More than 9 million HOYA preloaded IOLs implanted worldwide

Vivinex™ iSert® provides outstanding delivery consistency and offers the following features: [16,17]

- Injector tip outer diameter of 1.70 mm
- Uni-directional slider
- Screw injector with fixed grip





Step A
Infuse the OVD into the injector through the infusion port. Fill up the area indicated by dotted lines.

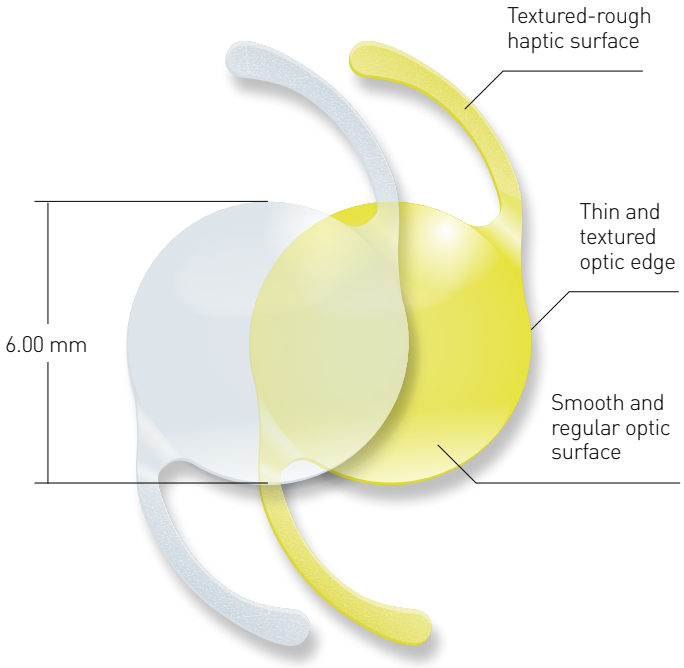
Step B
Press the release tabs, lift up and remove the cover from the case.

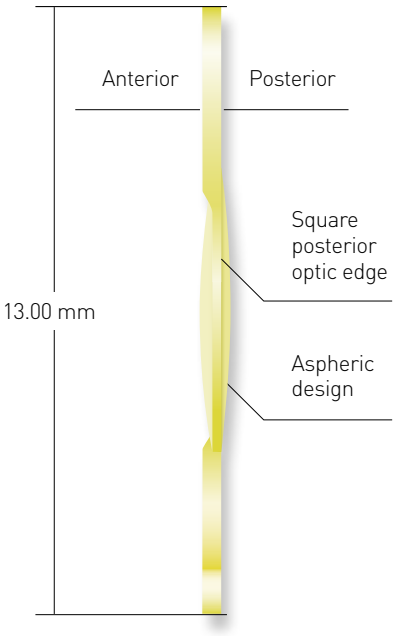
Step C
Hold body with thumb and push the slider slowly forward until it stops. Remove the injector from the case.

Step D
Carefully insert the injector tip into the eye through the incision, keeping the slit of the tip in a downward position. Slowly rotate the injector knob clockwise, to inject the lens into the capsular bag.

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

Technical characteristics





Vivinex™ iSert®				
Model name	**XC1 | XY1**			
Optic design	Aspheric design with square, thin and textured optic edge			
Optic & haptic materials	Hydrophobic acrylic Vivinex™ with UV-filter (Model XC1), with UV- and blue light filter (Model XY1)			
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	**Vivinex™ iSert®** 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.

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