

Vivinex™ iSert®

UNPRECEDENTED CLARITY OF VISION



- 1 Clinical Evaluation of the HOYA Vivinex™ IOL, HOYA data on file DoF-PHIV-101-SP2-12mIR-31082018 (2018).
 - 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 Meacock W, et al. The Effect of Texturing the Intraocular Lens Edge on Postoperative Glare Symptoms. Archives of Ophthalmology 2002; Vol 120: 1294-1298.
- * Trademarks are the property of their respective owners.

The preloaded **Vivinex™ IOL** provides unprecedented clarity of vision in the proven **Vivinex™ iSert®** injector

HOYA
SURGICAL OPTICS

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HOYA
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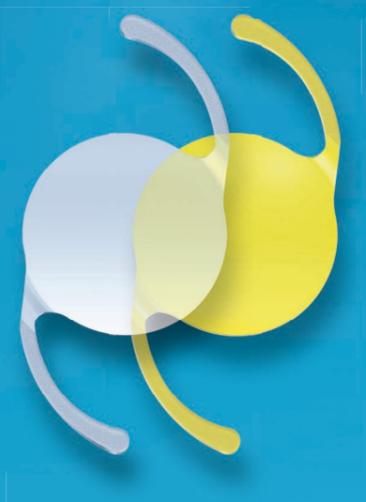
Vivinex™

Unprecedented clarity of vision

Designed to provide outstanding optical quality, Vivinex™ offers unprecedented clarity of vision for patients suffering from cataract. Product quality, trust, 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.

- Glistening-free hydrophobic acrylic IOL material^{1,3}
- Proprietary aspheric optic design for improved image quality⁵
- Active oxygen processing treatment and sharp optic edge to reduce PCO¹

More than
1,000,000
Vivinex™
IOLs sold



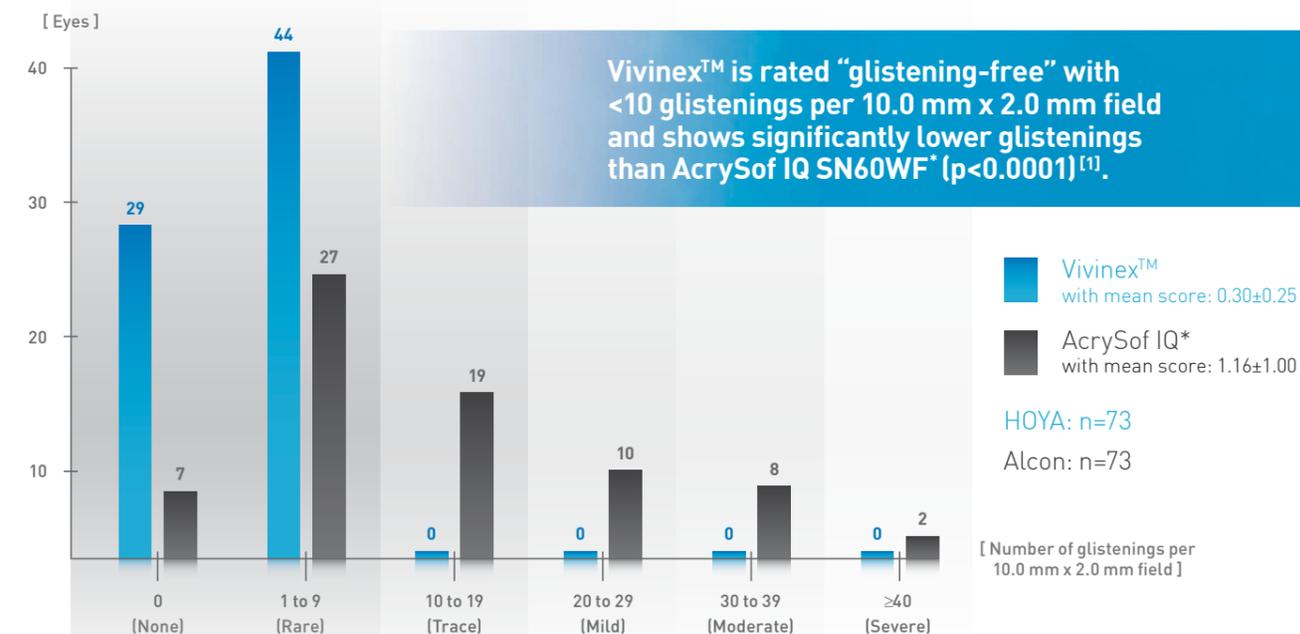
Hydrophobic acrylic Vivinex™ with UV-Filter (Model XC1), with UV- and blue light filter (Model XY1)



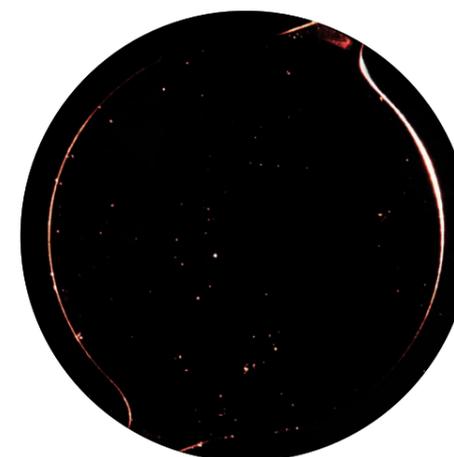
Glistening-free hydrophobic IOL material

A clinical study was conducted to independently compare Vivinex™ (Model XY1) with Alcon AcrySof IQ SN60WF*. Interim results show glistening formation after 12-months post-op^[1].

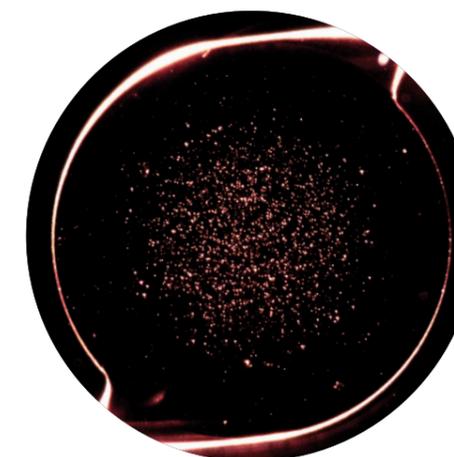
Clinical comparison of glistenings^[2]



Microscope images for evaluation of in vitro glistening formation at 14x^[3]



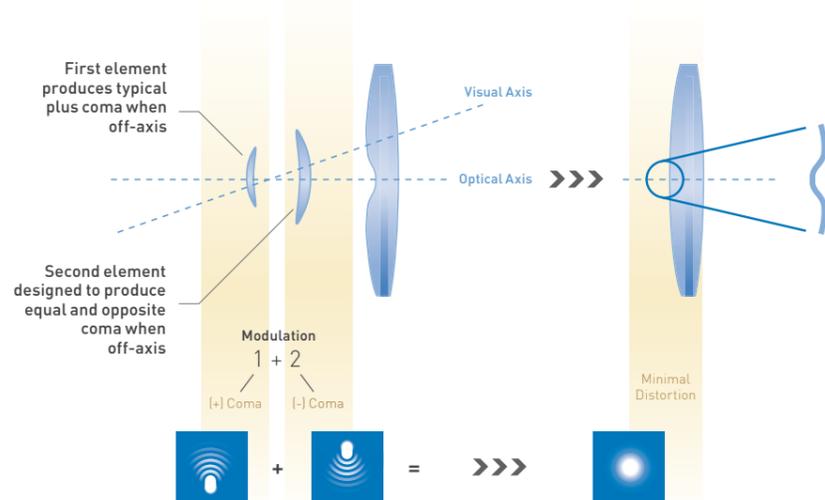
Vivinex™ XY1 (HOYA)
Grade 0 (glistening-free), based on Miyata et al.^[4] with 11.6 ± 5.7 MV/mm²



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 independent 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].



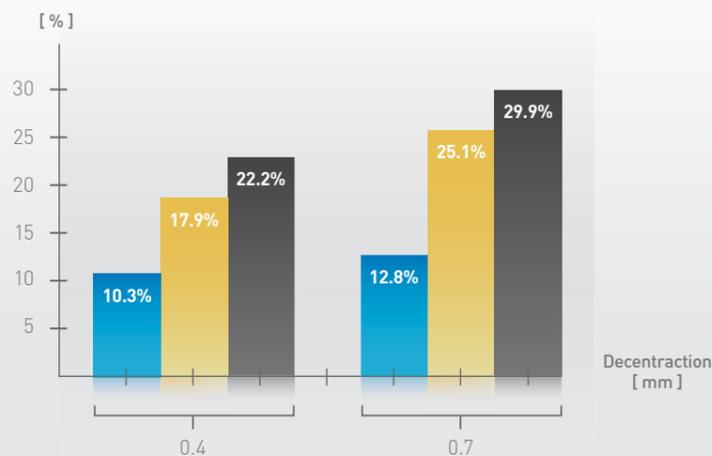
The innovative aspheric optics of Vivinex™ reduce spherical aberration without incurring significant susceptibility to decentration-associated coma^[5].

Reduced coma caused by off-axis alignment

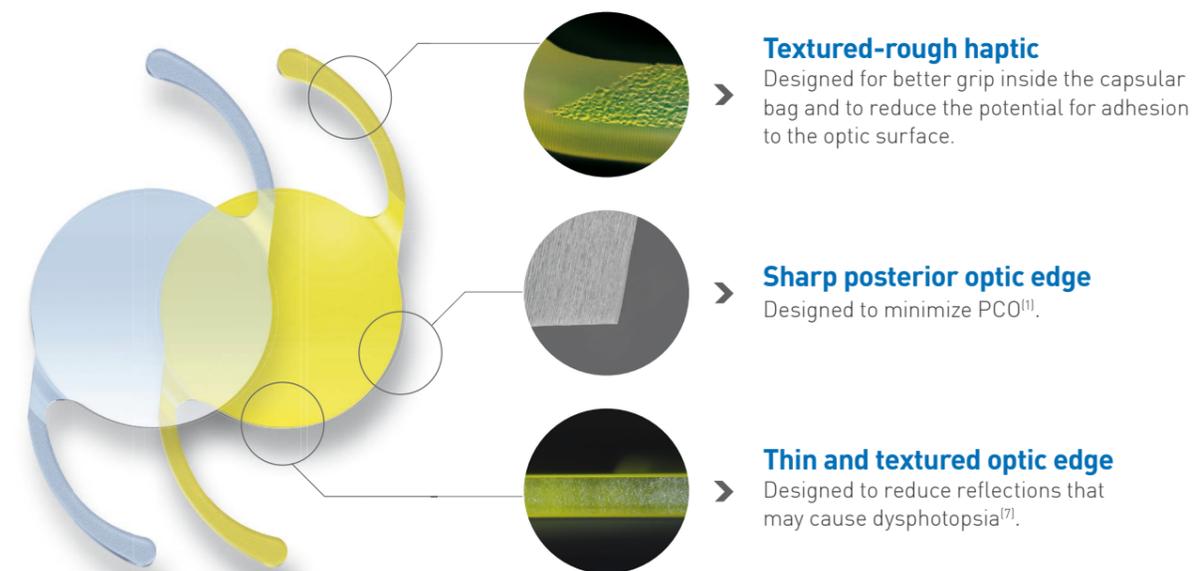
In the presence of decentration Vivinex™ induces less coma when compared with other leading competitor IOLs at 4.0 mm pupil diameter.^[5]

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]

- Vivinex™ XY1 (HOYA)
- Tecnis 1P ZCB00V (J&J)*
- AcrySof IQ SN60WF (Alcon)*



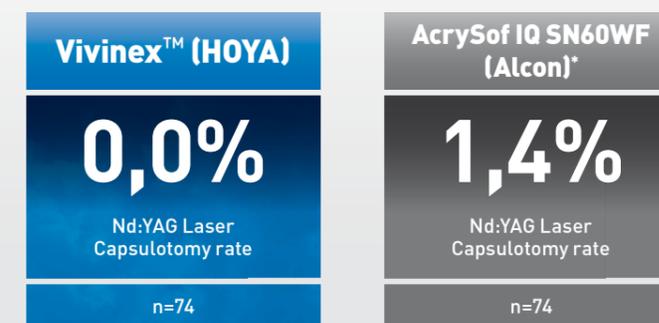
Vivinex™ IOL design



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

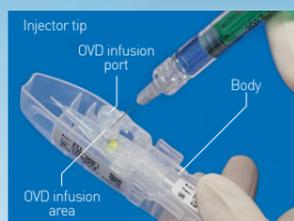
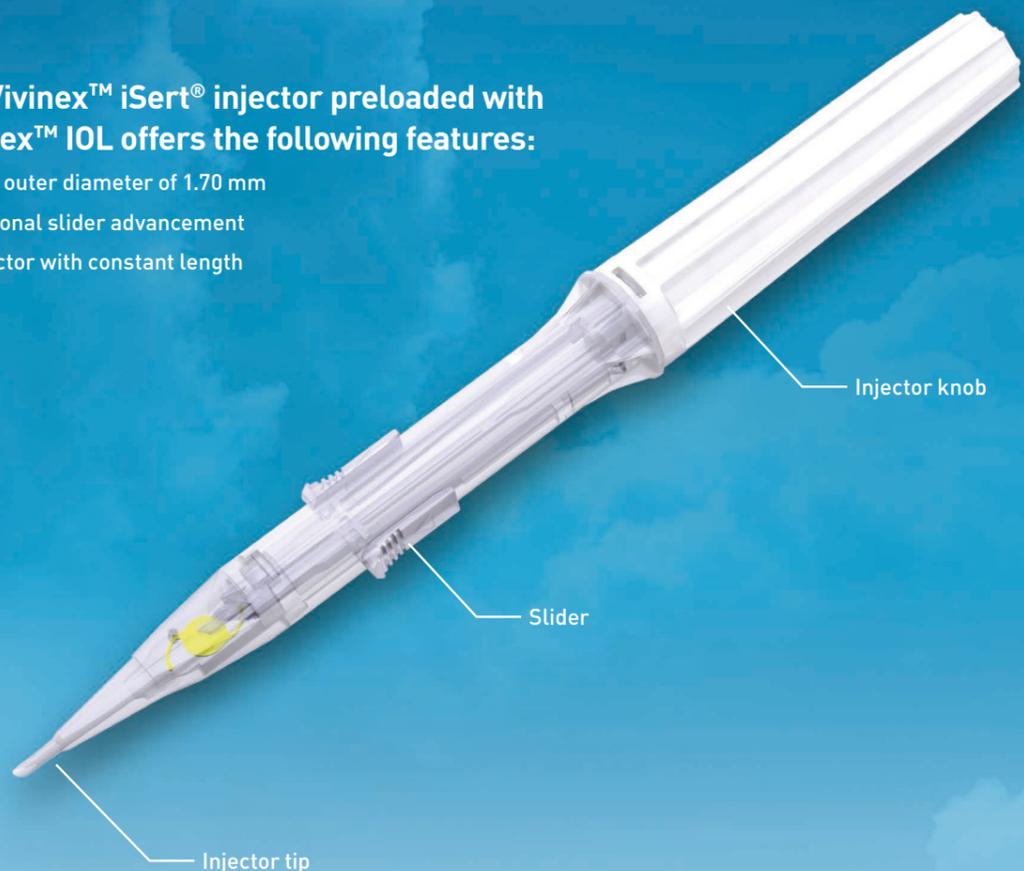


In comparison to Alcon's AcrySof IQ SN60WF* the Vivinex™ XY1 shows a lower Nd:YAG Laser Capsulotomy rate at 12 months post-op^[1].

More than 7 million HOYA preloaded IOLs sold worldwide

Proven Vivinex™ iSert® injector preloaded with the Vivinex™ IOL offers the following features:

- Injector tip outer diameter of 1.70 mm
- Uni-directional slider advancement
- Screw injector with constant length



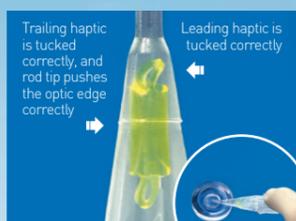
Step A
Infuse the OVD into the injector through the infusion port. Fill up the area indicated by dotted lines.



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



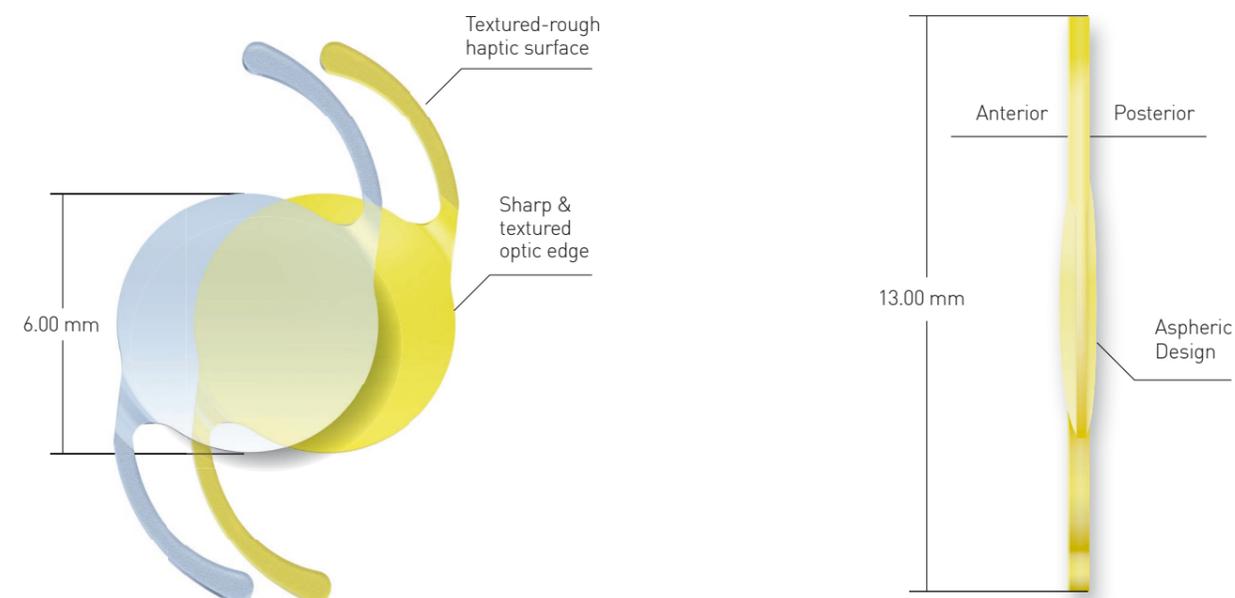
Step C
Hold body with thumb and push the slider slowly forward until it stops. Remove the injector from the case.



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 sharp textured optic edge			
Optic & Haptic Materials	Hydrophobic acrylic Vivinex™ with UV-filter (Model XC1) with UV- and blue light filter (Model XY1)			
Haptical Design	Textured-rough haptic surface			
Dimensions (Optic/OAL)	6.00 mm / 13.00 mm			
Power	+6.00 to +30.00 dpt. (in 0.50 D increments)			
Nominal A-Constant*	118.9			
Optimized Constants**	Haigis	a0 = -0.278	a1 = 0.215	a2 = 0.201
	Hoffer Q	pACD = 5.71		
	Holladay 1	sf = 1.94		
	SRK/T	A = 119.2		
Front injector tip outer diameter	1.70 mm			
Injector	Vivinex™ iSert® preloaded			

* The mentioned A-Constant is presented as a guideline only for lens power calculations. It is recommended that the A-Constant measurement be customized based on the surgeon's experience and measuring equipment.

**Source: <https://iolcon.org> Calculated from 911 patient data as of August 17, 2018