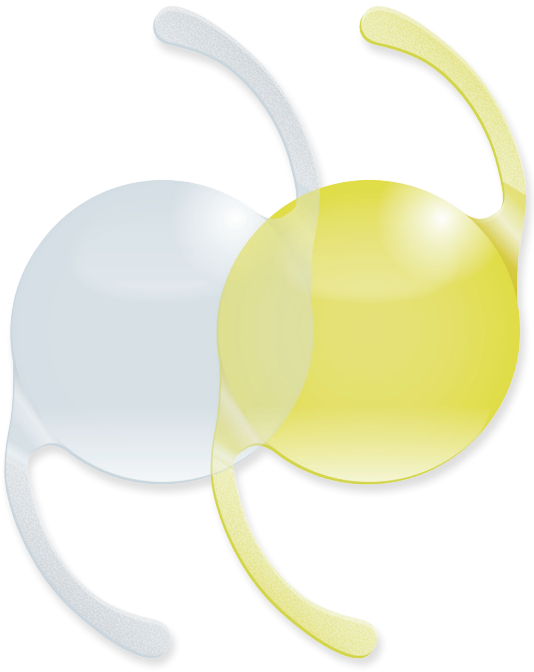
Vivinex iSert®

Long-term quality of vision is what every patient expects

Innovative combination of HOYA technologies provides:

- 1-piece aspheric lens with Vivinex™ hydrophobic acrylic material
- **Unique** surface treatment[1] designed to prevent PCO
- Long term **transparency** based on in vitro testing
- **Preloaded** iSert® System

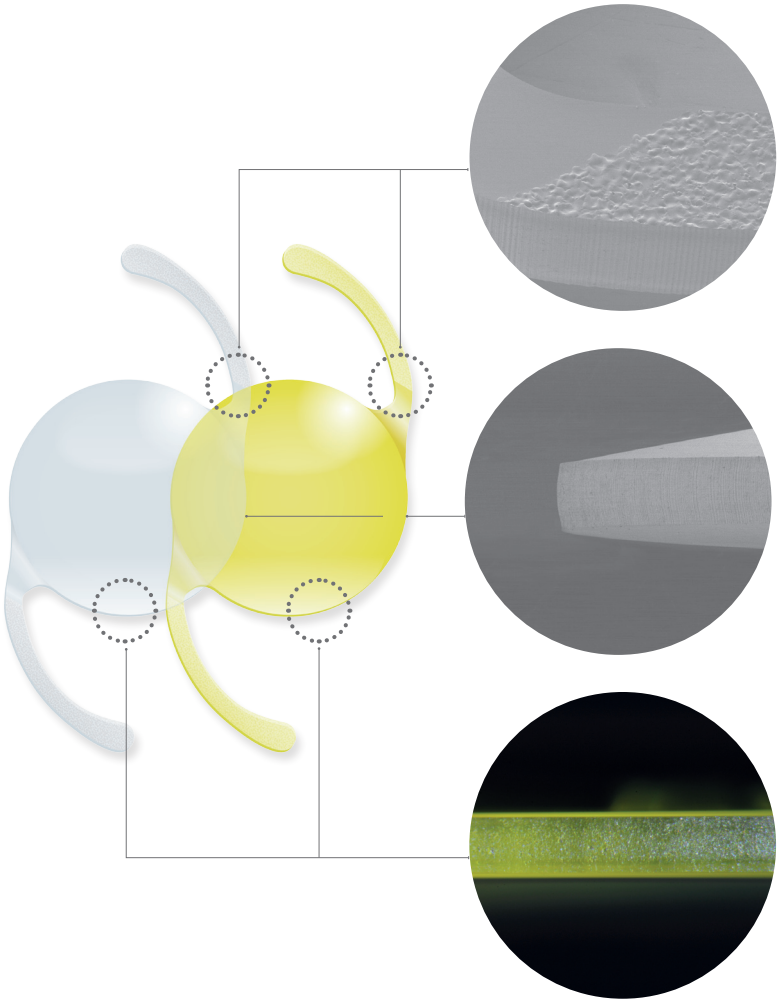


Model XC1 Model XY1

HOYA SURGICAL OPTICS

1. Patent No.: US8088314 B2

Distinctive IOL design



Textured-rough Haptic

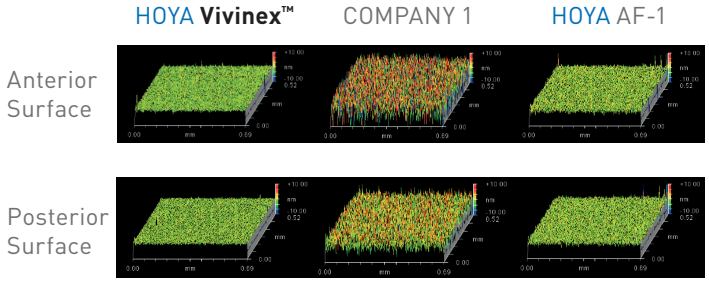
- Designed to reduce the potential for adhesion to the optic surface and to grip the capsular bag

Sharp Posterior Optic Edge

- Radius of curvature of less than 10 µm[4]
- A sharp posterior edge reduces PCO[2]

Optic Edge Texturing Finish

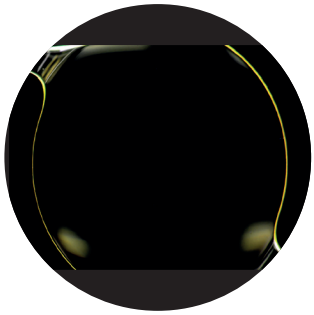
- Designed to reduce reflections that may cause dysphotopsia[3]



The HOYA family of IOLs have smooth anterior and posterior optic surfaces.[4]

2. Nishi O, Nishi K, Akura J. Speed of capsular bend formation at the optic edge of acrylic, silicone, and poly(methyl methacrylate) lenses. J Cataract Refract Surg 2002; 28(3):431-437.
3. Meacock W, et al. The Effect of Texturing the Intraocular Lens Edge on Postoperative Glare Symptoms. Archives of Ophthalmology 2002; Vol 120: 1294-1298.
4. Data on file

Clarity[5] and unique optics

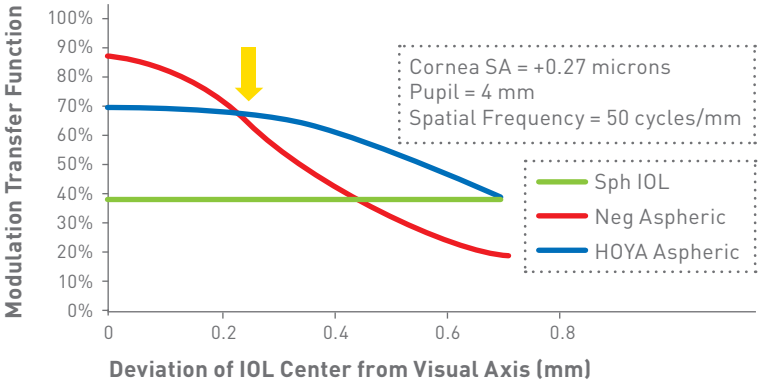


Vivinex™ did not develop glistenings during *in vitro* testing between 23°C and 35°C (Glistening Grade 0)[5]

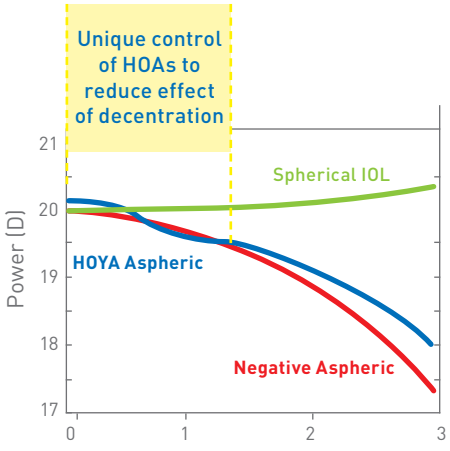
Patented Aspheric Balanced Curve (ABC) Optic Design[6]

Designed to provide a high quality image that is more tolerant to Coma caused by lens decentration and tilt[6]

Theoretical Eye Model



SA = Spherical aberration

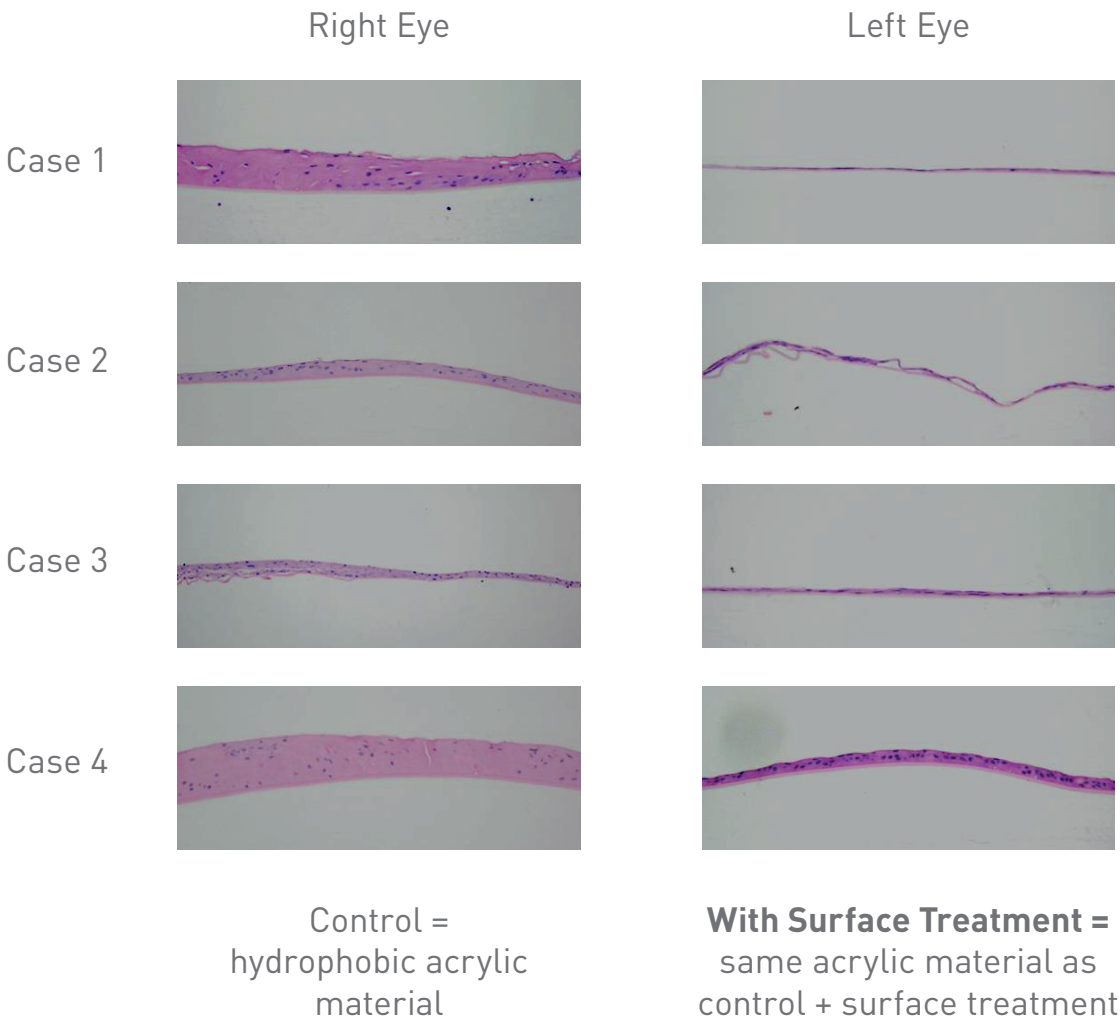


HOA = Higher-order aberrations

5. Data on file, in: Study result of the The David J Apple International Laboratory for Ocular Pathology, University Hospital Heidelberg. Report on file
6. Patent No.: US8647383 B2

Low levels of PCO[7] in *in vivo* tests

- **Vivinex™ IOLs are exposed to a unique** UV/Ozone surface treatment which is designed to reduce rates of PCO[1]
- Rabbits implanted with Vivinex™ showed a low level of PCO[7]

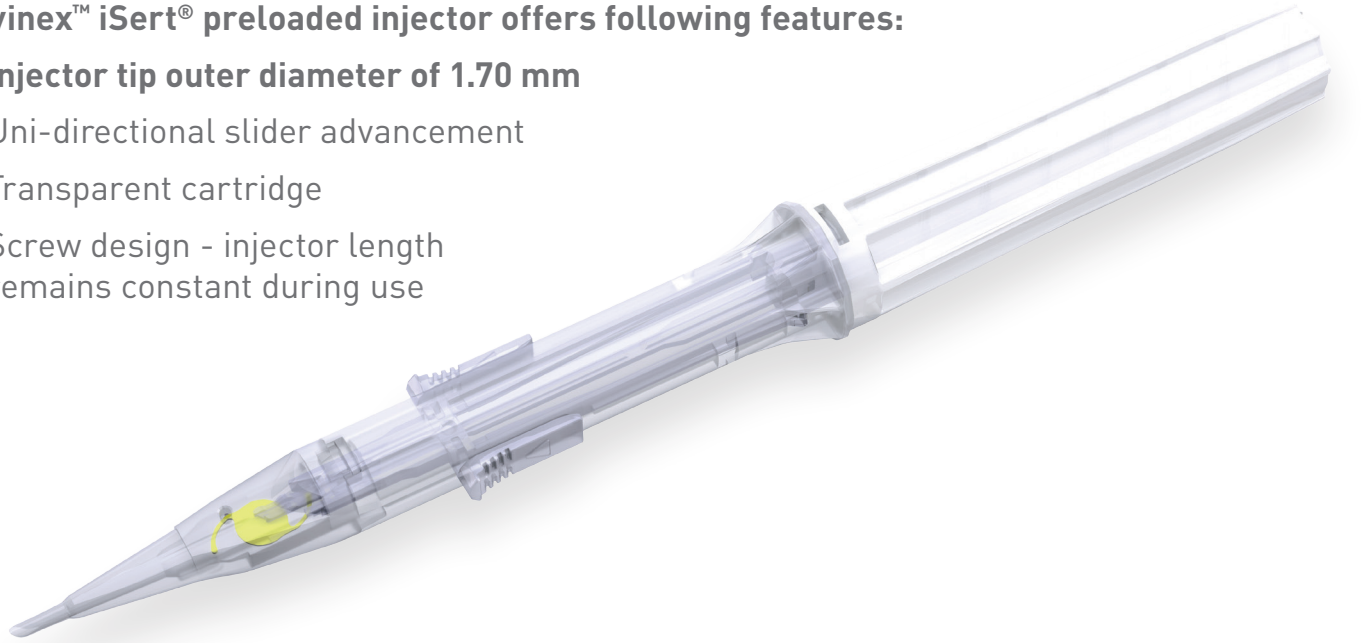


7. Hiroyuki Matsushima, et al. Active oxygen processing for acrylic intraocular lenses to prevent.posterior capsule opacification. J Cataract Refract Surg. 2006; 32:1035-1040.

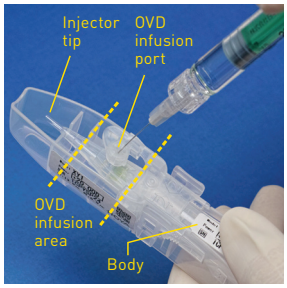
Small incision size reduces surgical induced astigmatism[8,9]

Vivinex™ iSert® preloaded injector offers following features:

- **Injector tip outer diameter of 1.70 mm**
- Uni-directional slider advancement
- Transparent cartridge
- Screw design - injector length remains constant during use



The handling shown below is intended as an illustrative summary and does not replace the Instruction For Use.



Step A

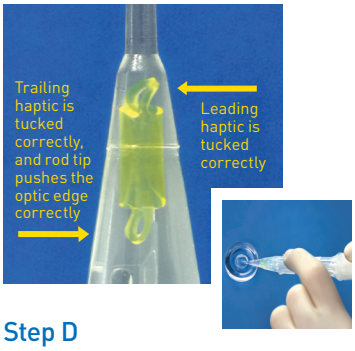
Infuse the OVD into the injector through the infusion port. Fill up the area indicated by dotted lines.

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.



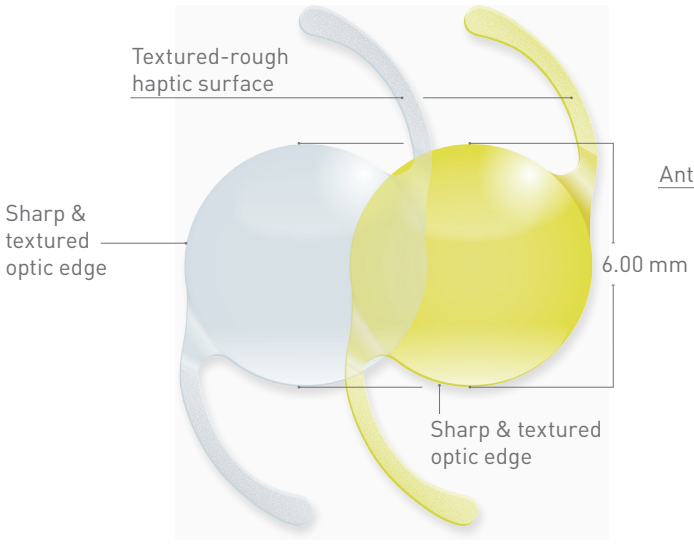
Step D

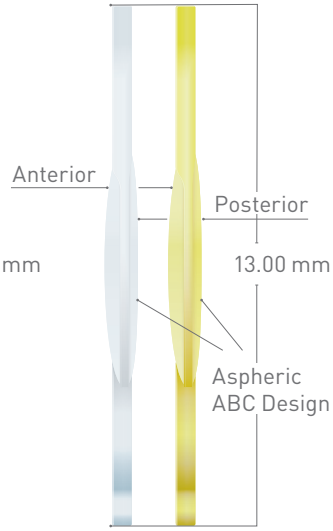
Carefully insert the injector tip into the eye through the incision, keeping the slit of the tip in a downward position. Slowly rotate the injector knob clockwise, to inject the lens into the capsular bag.

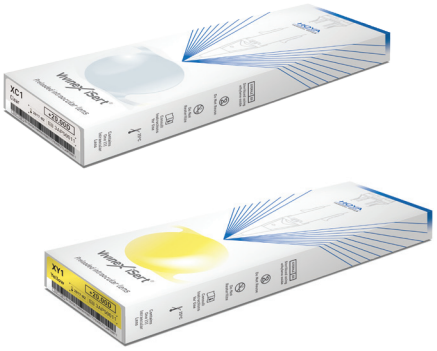
8. Haotian Lin, et al., Coaxial Microincision Cataract Surgery versus Standard Coaxial Small-Incision Cataract Surgery: A Meta-Analysis of Randomized Controlled Trials, PloS One 2016,11(1) published online 2016 Jan 8
9. Hayashi K.et al. Postoperative corneal shape changes: microincision versus small-incision coaxial cataract surgery, J Cataract Refract Sug. 2009 Feb, 35(2):233-239

Preloaded System
Hydrophobic Acrylic IOL

Vivinex iSert® Models XC1/XY1







Model XC1 Model XY1

Model Name	Vivinex™ iSert® **XC1,** Vivinex™ iSert® **XY1**
Optic Design	Aspheric ABC Design[6] with sharp textured optic edge
Optic & Haptic Materials	Hydrophobic acrylic Vivinex™ with UV filter (model XC1), with blue light filter (model XY1)
Haptic Design	Textured-rough haptic surface
Dimension (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 a0 = -0.905 a1 = 0.230 a2 = 0.229 Hoffer Q pACD = 5.74 Holladay 1 sf = 1.98 SRK/T A = 119.2 SRK II A = 119.5
Front injector tip outer diameter	1.70 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.

** Calculated from 531 patient data on file. (as of Dec. 9, 2016)

Singularly Focused. Globally Powered.™

Some of the product and/or specific features as well as the procedures featured in this document may not be approved in your country and thus may not be available there. Design and specifications are subject to change without prior notice as a result of ongoing technical development. Please contact our regional representative regarding individual availability in your respective market.

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