Vivinex™ Toric multiSert™

CLARITY & CONTROL COMBINED WITH OUTSTANDING ROTATIONAL STABILITY

Vivinex™ Toric IOL offers **clarity of vision** and **outstanding rotational stability**

Delivered by **multiSert™**, providing **unmatched control at your fingertips**

HOYA
SURGICAL OPTICS

Vivinex™ Toric Clarity and outstanding rotational stability

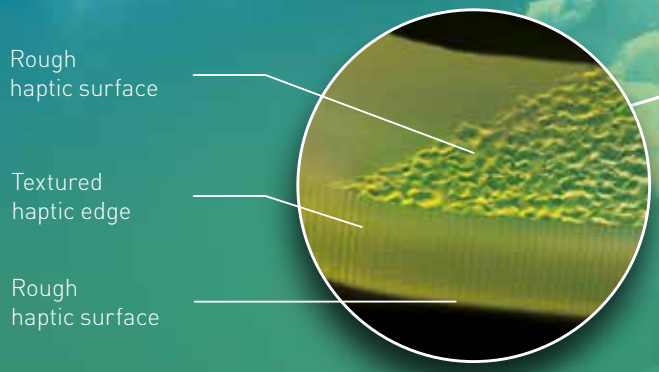
Designed for outstanding optical quality, Vivinex™ Toric multiSert™ has proven rotational stability for precise astigmatism correction and provides patients with an astigmatic cornea with clarity of vision. Product quality, dedication and attention to detail are deeply rooted in our Japanese heritage, and with 2 million lenses implanted worldwide, surgeons' trust in Vivinex™ is proven.

Vivinex™ Toric:

- 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]
- Median rotation 1.1° (range 0.0° – 5.0°)
  100% of lenses (n=103) had ≤ 5° of rotation from their initial axis at end of surgery through all follow up visits at 1 hour, 1 week, 1 month and 6 months[11]

Textured-rough haptic surface for better grip

Vivinex™ haptics have different surface structures. They provide better grip inside the capsular bag and are designed to reduce the potential for adhesion to the optic surface.

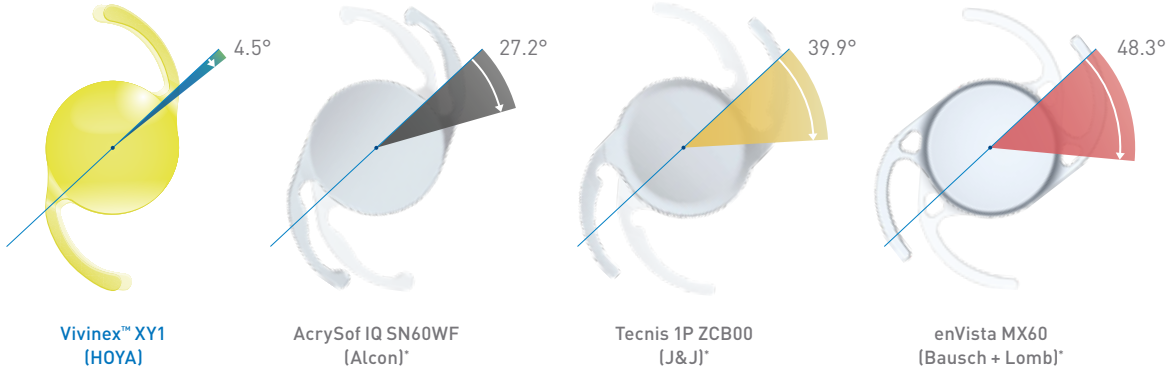


Reliable outcomes through outstanding rotational stability [11]

Early clinical results with the Vivinex™ preloaded IOL platform at the University of Vienna confirm outstanding rotational stability. In a group of 103 eyes, no lens rotated more than 5 degrees from orientation at the end of surgery to 6 months postoperatively.

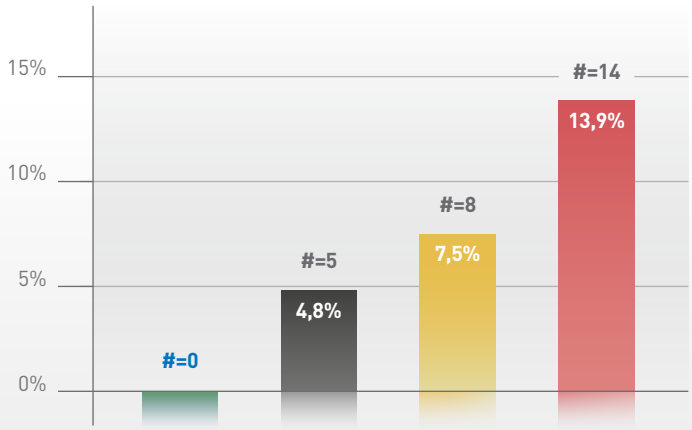
The Vivinex™ IOL platform shows outstanding rotational stability between surgery and one week post op, without outliers, when compared to AcrySof*, Tecnis* and enVista*. [11,12]

Maximum rotation values observed in the first week following surgery [11,12]



In the timeframe of up to 6 months post-op, no implanted Vivinex™ IOL rotated more than 5° from initial axis, in comparison to 4.8% of the AcrySof* IOL, 7.5% of the Tecnis* IOL and 13.9% of the enVista* IOL. [11,12]

Percentage and total number of IOLs that rotated more than 5° between end of surgery and 6 months postoperatively



Vivinex™ XY1 (HOYA) n=103

AcrySof IQ SN60WF (Alcon)* n=104

Tecnis 1P ZCB00 (J&J)* n=106

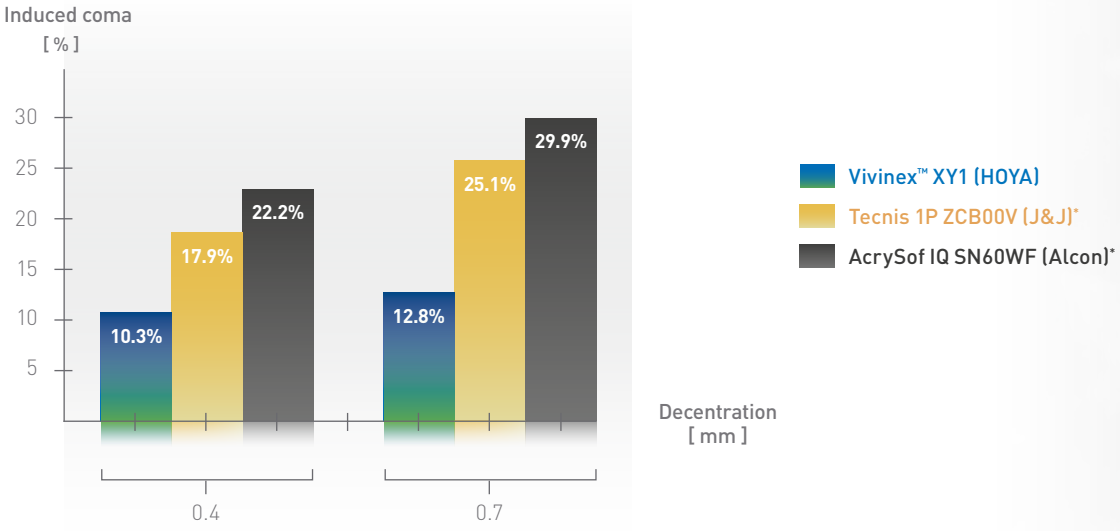
enVista MX60 (Bausch + Lomb)* n=101

Most studies published about rotational stability of toric IOLs do not measure early rotation from the initial axis at end of surgery. The baseline for rotation measurements is often the axis of alignment at 1 day postoperative.[11,12]

Proprietary aspheric optic design for improved image quality

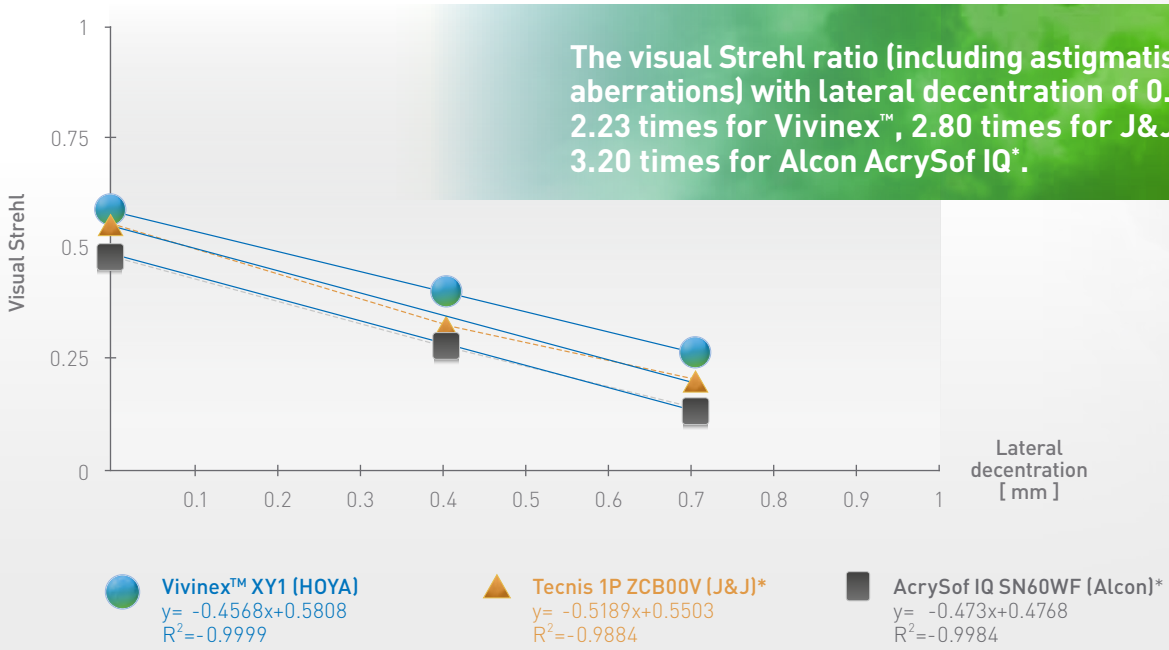
In the presence of decentration Vivinex™ minimises coma when compared with other aspheric IOLs at 4.0 mm pupil diameter.[3]
Studies have shown that the mean decentration of an IOL following cataract surgery is 0.4 ± 0.2 mm with a range up to 1.7 mm.[13]

Reduced coma caused by off-axis alignment



Reduced impact on optical quality caused by off-axis alignment[3]

The visual Strehl ratio (including astigmatism and high order aberrations) with lateral decentration of 0.7 mm decreased 2.23 times for Vivinex™, 2.80 times for J&J Tecnis 1P* and 3.20 times for Alcon AcrySof IQ*.



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

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

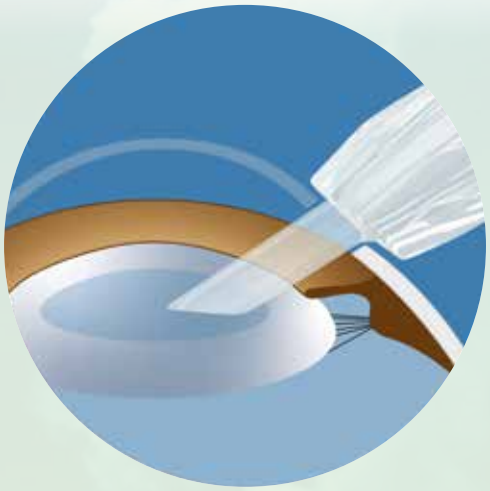
Two-handed screw injection

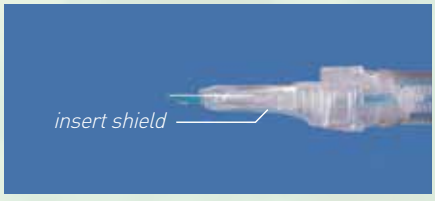
Uniquely designed adjustable *insert shield* for precise injector tip insertion depth management

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

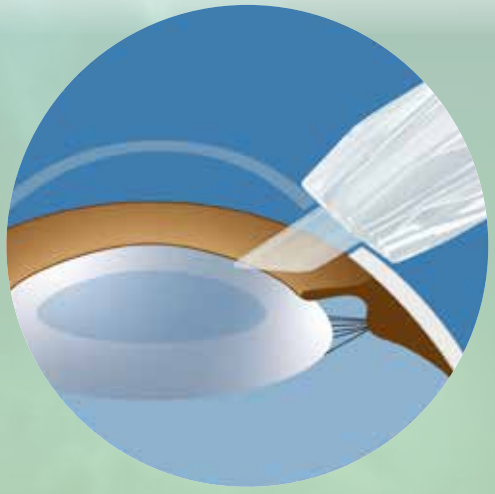


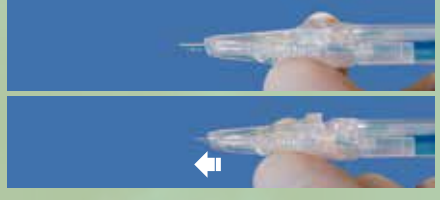


insert shield:
default position

or

Delivery through incision wound tunnel





insert shield:
advanced position

multiSert™ provides outstandingly consistent and predictable IOL delivery

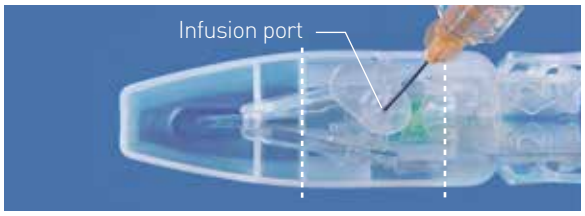
100 %
Of leading and trailing haptics were consistently tucked correctly [14]

0 %
Complications or adverse events [14]

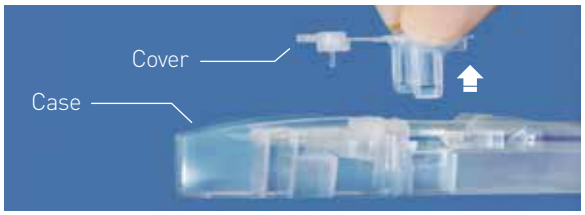
0 %
Broken injector tips after IOL release [14]

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]

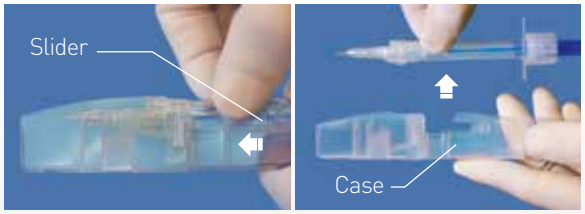
Ready for implantation in four easy preparation steps



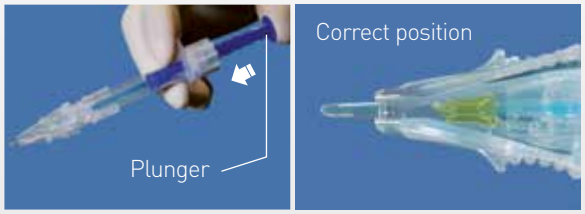
Step 1:
Infuse the sodium hyaluronate OVD into the injector through the infusion port.



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.

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VIVINEX™ TORIC OFFERS CLARITY OF VISION AND OUTSTANDING ROTATIONAL STABILITY

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- **Active oxygen processing treatment**, a **smooth surface** and **square optic edge** to reduce PCO[1,4,5,6,7,8,9,10]
- **Median rotation 1.1°** (range: 0.0° – 5.0°)
  100% of lenses (n=103) had **⩽5° of rotation** from their initial axis at end of surgery through all follow up visits **at 1 hour, 1 week, 1 month and 6 months**[11]

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]

Introducing the HOYA Toric Calculator 4

According to several studies, standard toric IOL calculations tend to result in a calculation error of astigmatic value. Most often in: [15]

- undercorrection of against-the-rule astigmatism (ATR)
- overcorrection of with-the-rule astigmatism (WTR).

The HOYA Toric Calculator (HTC) 4 can take account of posterior corneal astigmatism in the calculation by giving the option to apply the Abulafia-Koch Regression formula.

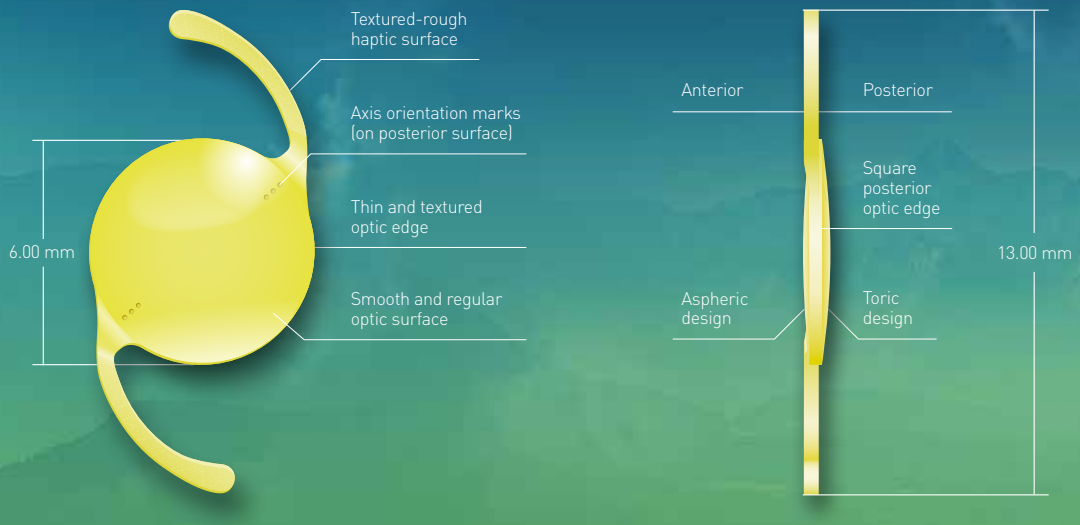
The Abulafia-Koch Regression, applied to a clinical patient cohort, has been shown to improve predictability of TIOL refractive outcomes.[15]

For Vivinex™ Toric IOL calculation please visit
www.HOYAtoric.com

The HTC 4 at a glance

- Choice of three different cylinder power options allows the doctor to select the most suitable IOL model based on residual astigmatism and axis
- Optional Abulafia-Koch Regression formula can account for the added astigmatic effect of the posterior cornea when measured by standard keratometry of the anterior corneal surface
- Option to display calculation results as plus (+) or minus (-) cylinder
- Adjustable keratometer index (default 1.3375)
- Optional axial length data entry to adjust the cylinder power of the toric IOL at the corneal plane
- Numerous different print and export options are available with customized orientation of the printed eye image

Technical characteristics



Vivinex™ Toric multiSert™				
Model name	**XY1A-SP**			
Optic design	Biconvex with square, thin and textured optic edge Anterior: Aspheric design Posterior: Toric design			
Optic & haptic materials	Hydrophobic acrylic Vivinex™ with UV- and blue light filter			
Haptic design	Textured-rough haptic surface			
Diameter (optic/OAL)	6.00 mm / 13.00 mm			
Power	+10.00 to +30.00 D (in 0.50 D increments)			
Cylinder power[16]	1.00 to 6.00 D (T2 to T9) T2 to T3 in 0.50 D increments T3 to T9 in 0.75 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			

Model XY1A-SP	Cylinder power at IOL plane	Cylinder power at corneal plane[17]
T2	1.00 D	0.69 D
T3	1.50 D	1.04 D
T4	2.25 D	1.56 D
T5	3.00 D	2.08 D
T6	3.75 D	2.60 D
T7	4.50 D	3.12 D
T8	5.25 D	3.64 D
T9	6.00 D	4.17 D

** 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.

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

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

3 Pérez-Merino, P.; Marcos, S. (2018): Effect of intraocular lens decentration on image quality tested in a custom model eye. In: Journal of cataract and refractive surgery 44 (7), p. 889–896.

4 Leydolt, C. et al. (2020): Posterior capsule opacification with two hydrophobic acrylic intraocular lenses: 3-year results of a randomized trial. In: American journal of ophthalmology 217 (9), p. 224-231.

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9 Farukhi, A. et al. (2015): Evaluation of uveal and capsule biocompatibility of a single-piece hydrophobic acrylic intraocular lens with ultraviolet-ozone treatment on the posterior surface. In: Journal of cataract and refractive surgery 41 (5), p. 1081–1087.

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11 Schartmüller, D. et al. (2019): True rotational stability of a single-piece hydrophobic intraocular lens. In: The British journal of ophthalmology 103 (2), p. 186–190.

12 Schartmüller, D. et al. (2020): Comparison of Long-Term Rotational Stability of Three Commonly Implanted Intraocular Lenses. In American journal of ophthalmology 220, pp. 72–81.

13 Harrer, A. et al. (2017): Variability in angle κ and its influence on higher-order aberrations in pseudophakic eyes. In: Journal of cataract and refractive surgery 43 (8), p. 1015–1019.

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

15 Abulafia, A. et al. (2016): New regression formula for toric intraocular lens calculations. In: Journal of cataract and refractive surgery 42 (5), p. 663–671.

16 At IOL plane.

17 Based on an average pseudophakic human eye.

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HOYA Medical Singapore Pte. Ltd | 455A Jalan Ahmad Ibrahim | Singapore 639939

HOYA Surgical Optics GmbH | De-Saint-Exupéry-Straße 10 | 60549 Frankfurt am Main | Germany
Hotline DE: Tel. +49 (0)800 664 2 664 | Fax +49 (0)800 774 2 774

hoyasurgicaloptics.com

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