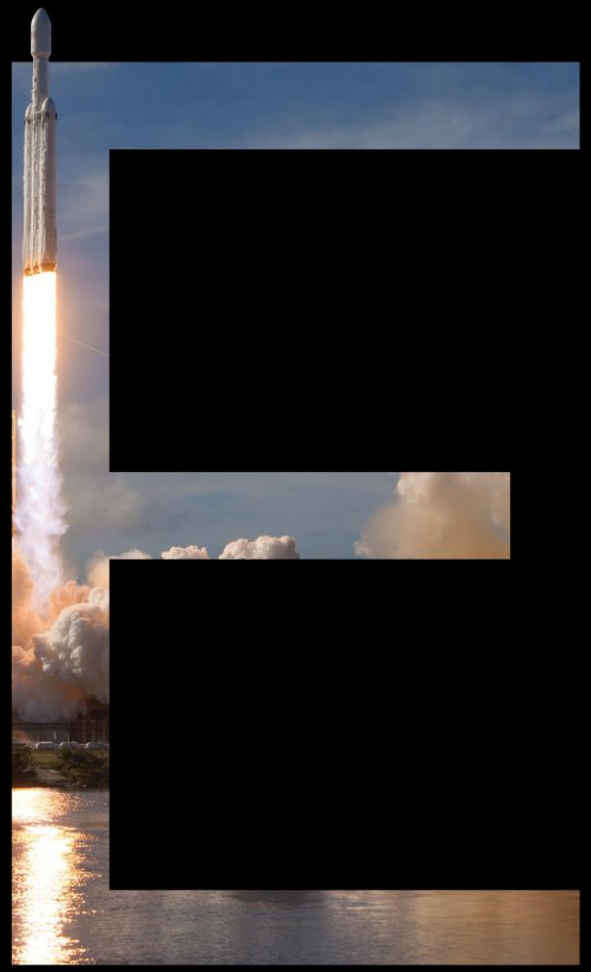
Vivinex Impress™

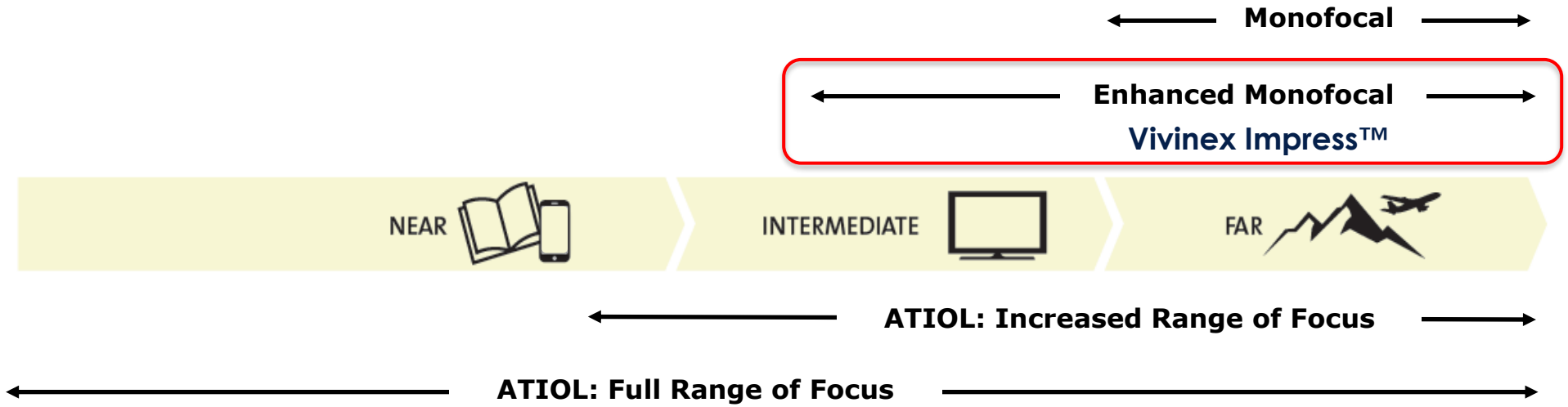
Marketing Update

August 2023



HOYA SURGICAL OPTICS

Categorization of enhanced monofocal IOLs



- Monofocal IOL designed to provide enhanced image quality with a wider range of focus
- The extended range of focus provided by an enhanced monofocal IOL (EMIOL) may provide superior intermediate vision performance compared to a standard monofocal IOL

In addition, an EMIOL does not compromise on:

- Distance visual acuity clinically equivalent to a standard monofocal IOL
- Incidence and intensity of photic phenomena be similar to that seen amongst patient groups implanted with a standard monofocal IOL

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Insights of enhanced monofocal IOLs in high volume cataract environments

Target Customers: Surgeons in high volume facilities conducting monofocal cataract procedures within the "best/enhanced" monofocal IOL segment.

High Volume cataract surgery facilities where the "best/enhanced" mono segment falls wholly within the government reimbursement system represent a significant opportunity.

- Cataract patients expect improved distance vision following surgery and toric IOLs are rarely used.
- Surgeons/staff/managers may be motivated to use Vivinex Impress because cataract patients may achieve higher satisfaction vs a standard aspheric monofocal at no extra cost.

  The benefits to patients:

  1. They may achieve a greater degree of spectacle independence for intermediate tasks
  2. There is no noticable downside, distance vision is not compromised, and the incidence of photic phenomena are equivalent to a monofocal
- The benefit for surgeons and staff may be:

  1. Efficiency in the OR due to the consistency of the preloaded multiSert delivery.
  2. Efficiency in the clinic because highly satisfied patients pass smoothly along standard treatment pathways with minimal follow ups required

Insights of enhanced monofocal IOLs in high volume cataract environments

The needs of centers focused on mitigating spectacle use amongst patients (cataract and CLE) who are paying fully out of pocket, co-paying, or privately insured can only be fully satisfied when Impress Toric is available

- Surgeons in this segment may choose to use an enhanced monofocal IOL, with or without using mini-monovision, to mitigate spectacle use in patients that:
  1. will not tolerate the reduced contrast or dysphotopsias that are part and parcel of diffractive designs, and to some extent of EDOF designs such as Vivity (in the presence of defocus)
  2. will not pay for the potentially greater spectacle independence offered by a trifocal or EDOF IOL

Competition

- J&J Eyhance created the enhanced monofocal segment as a sub segment of the "best monofocal" category. They are pursuing a mixed upgrade/competitive switch strategy with the objective of maintaining and growing share.
- They are active in both the high volume cataract centres and, due to the toric option, centres wishing to mitigate spectacle dependence
- Performance of the IOL is at best "not superior" to Vivinex Impress in multiSert. Due to the design of the Eyhance optics, patients may experience refractive shifts when going from dark to light environments, and the depth of focus achieved by patients has been presented to vary significantly. Achieving less DoF in longer eyes due ELP and the optical design.
- Other competitors; including BVI IsoPure, Rayner RayOne EMV, Teleon Lentis Quantum, and OphthalmoPro Zoe. All have compromises, be it no toric availability, injector system, and/or IOL material

Vivinex Impress™ IOL

RANGE OF VISION

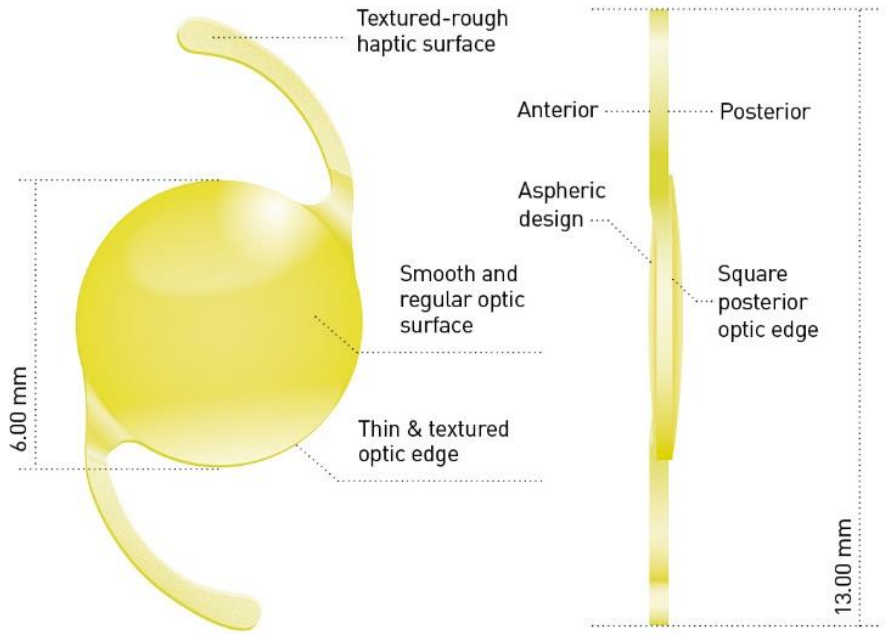
NEAR

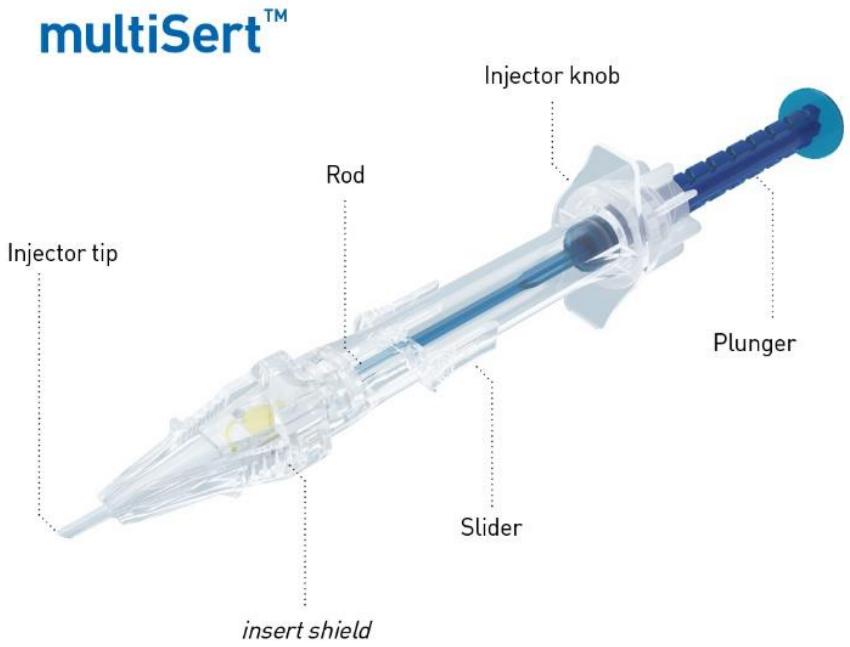
INTERMEDIATE

FAR

Standard monofocal aspheric IOL

MODEL **XY1-EM**





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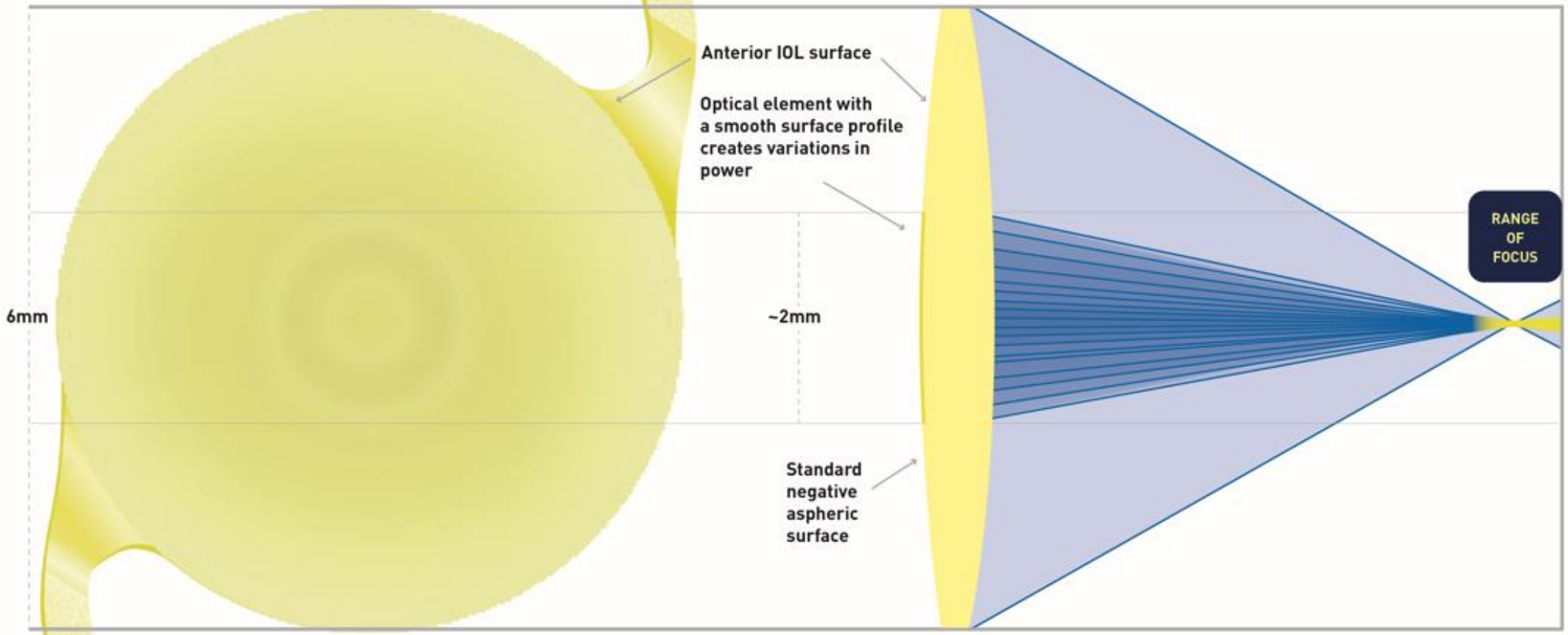
Mechanism Of Action

Topographic representation of the Vivinex Impress™ anterior surface illustrates power variations

Representation of Vivinex Impress™ side view

Representation of light refracted by the Vivinex Impress™ optic to create an extended range of focus



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

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The foundation of our new campaign is the early interim results of the VIEM-101-COMP multicentre, randomised, prospective clinical study

Interim COMP Study Data

HOYA SURGICAL OPTICS

The foundation of our new campaign is the early interim results of the VIEM-101-COMP multicentre, randomised, prospective clinical study

- Main objective: To support claim of 1-line intermediate VA improvement compared to a standard monofocal aspheric IOL
- 190 bilateral subjects enrolled
    - 130 Vivinex Impress
    - 60 Alcon AcrySof IQ
- Final exam at 12 to 14 months post-op. around March/April 2024
- 14 Centers
    - Germany (7), Spain (3), Poland (2), Philippines (2)

As of today, we have limited clinical data to share <u>as a trend indicator only:</u>

- **73 subjects (49 Vivinex Impress and 24 Acrysof IQ) with 1 month exam**
- **45 subjects (29 Vivinex Impress and 16 Acrysof IQ) with 4-6 months exam**

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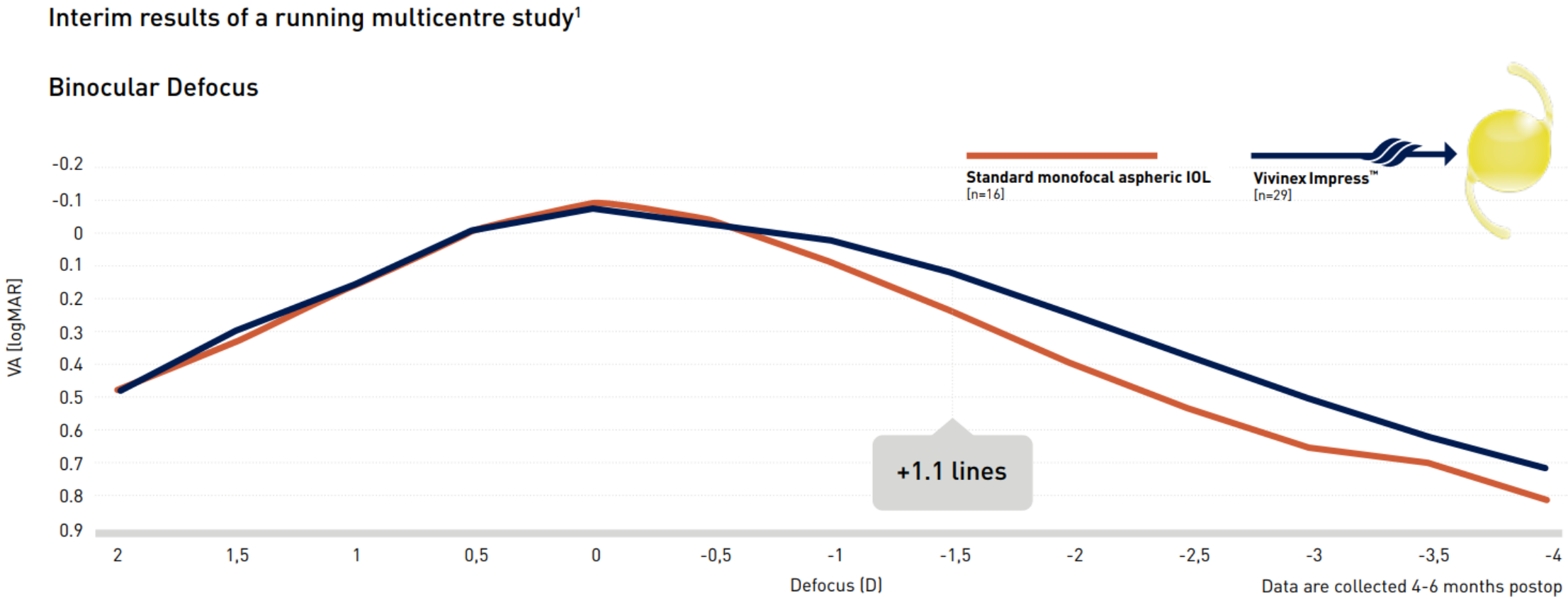
Vivinex Impress™ provides >1 line of binocular visual acuity improvement at 66 cm



- Vivinex Impress™ provides the same best-corrected mean distance acuity as a standard monofoal aspheric IOL
- Vivinex Impress™ improves intermediate visual acuity at 66 cm (-1.5 D defocus) by more than 1 line

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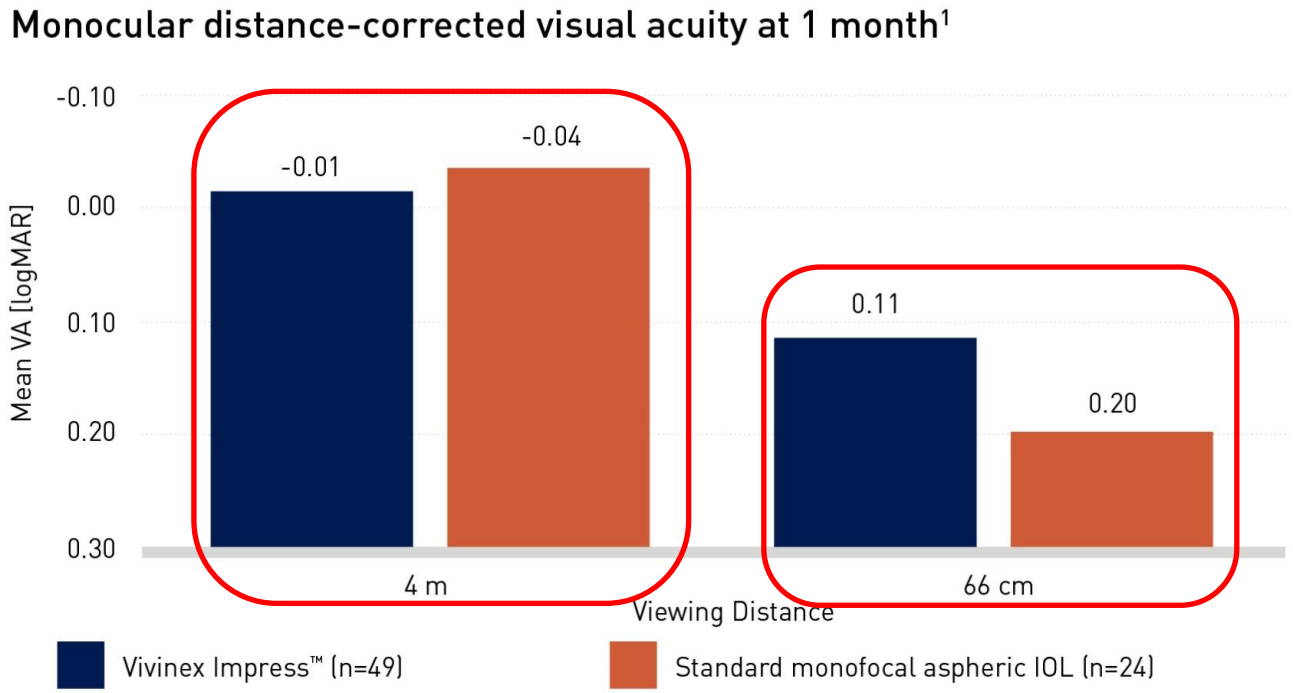
Vivinex Impress™ improves intermediate vision

- No difference in best-corrected mean distance acuity at distance
- ~1 line improvement in distance-corrected intermediate VA at 66 cm in the Vivinex Impress group



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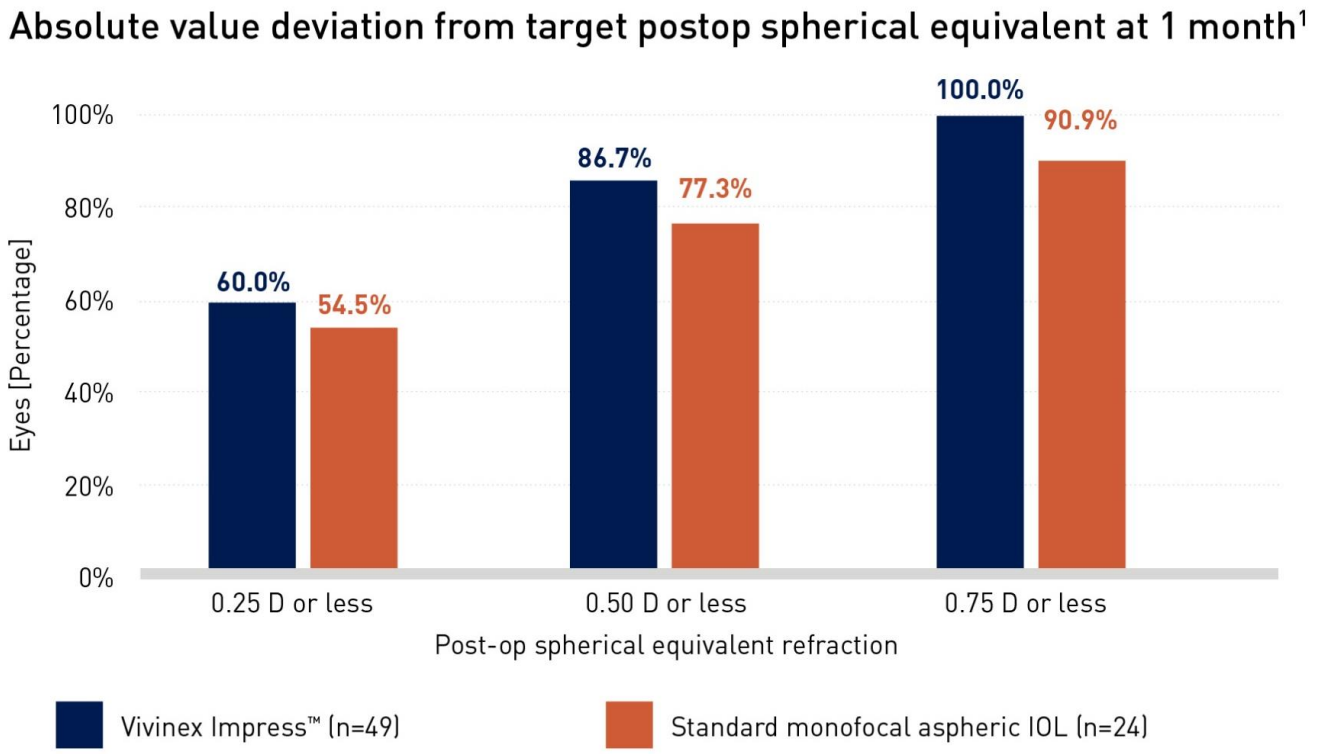
Vivinex Impress™ provides consistant refractive predictability

- Refractive predictability was excellent in both study groups
  - within 0.25 D of target: 60% vs 55%
  - within 0.50 D of target: 87% vs 77%
  - within 0.75 D of target: 100% vs 91%



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Global CLEARlog registry data demonstrate the enhanced monofocal performance of Vivinex Impress™

Real World Clinical Data

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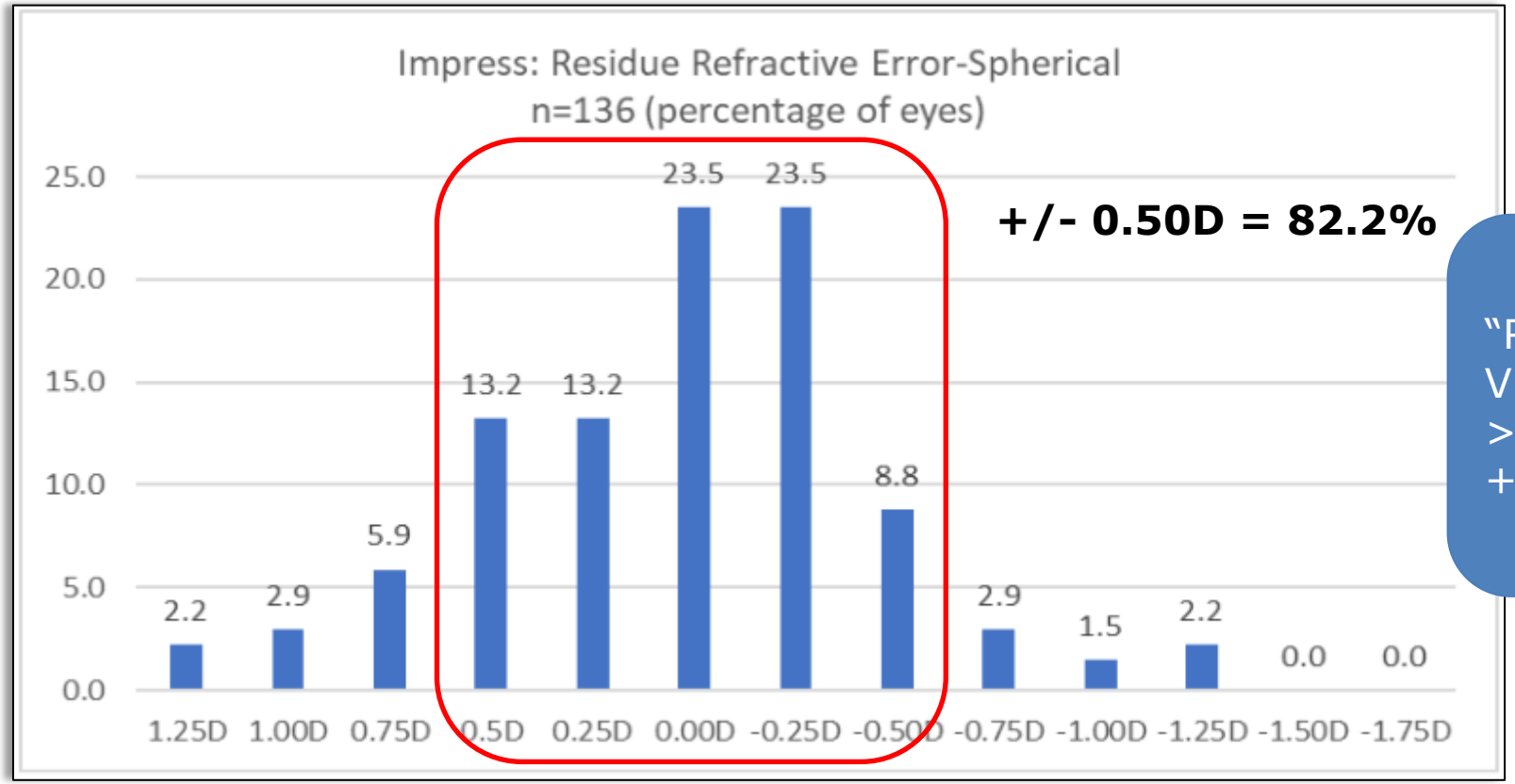
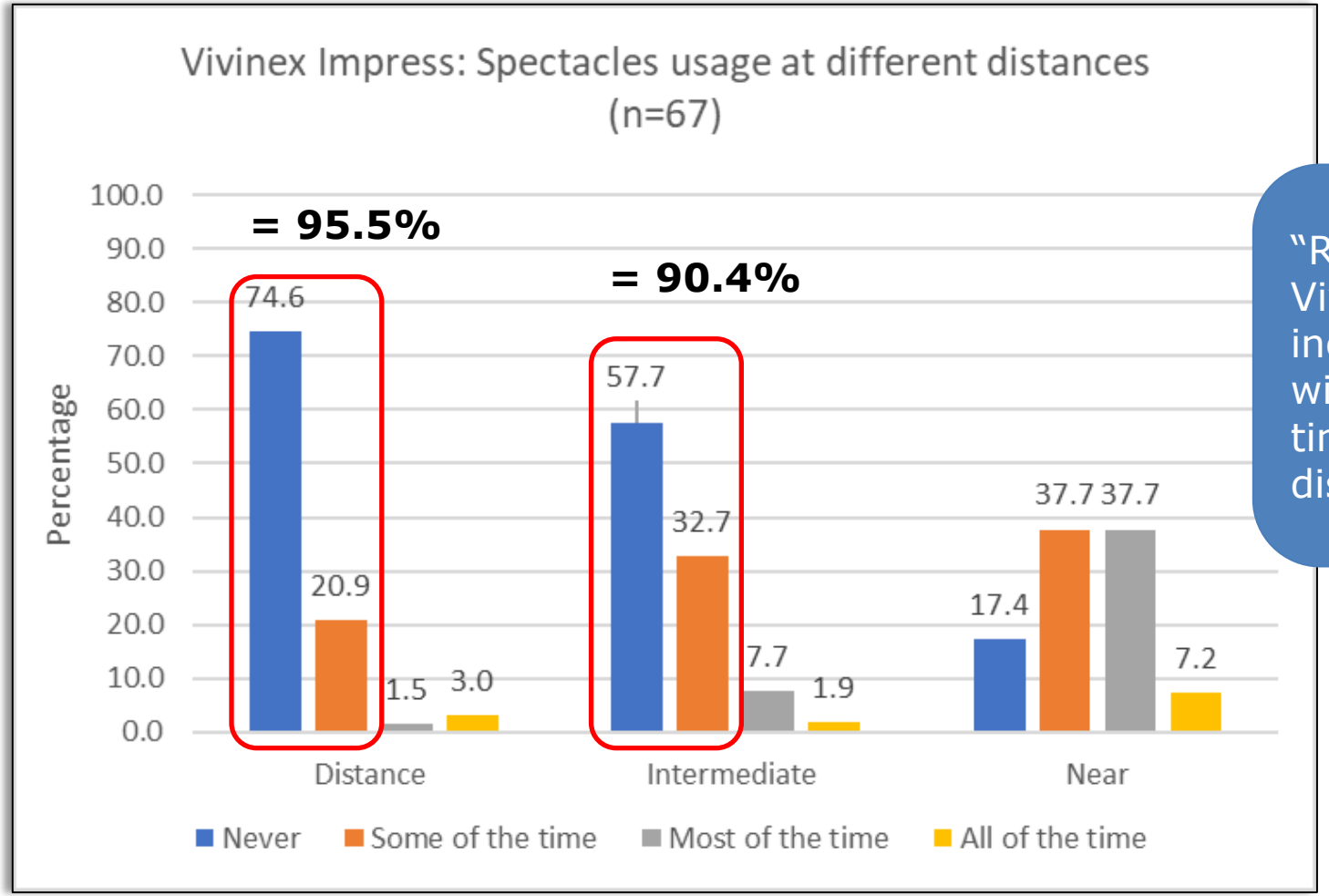
CLEARlog registry data
Vivinex Impress™ has an excellent refractive predictability, consistent with COMP clinical data



"Real world data" for Vivinex Impress™ shows > 80% of eyes are within +/- 0.50D.

Data as of July 2023

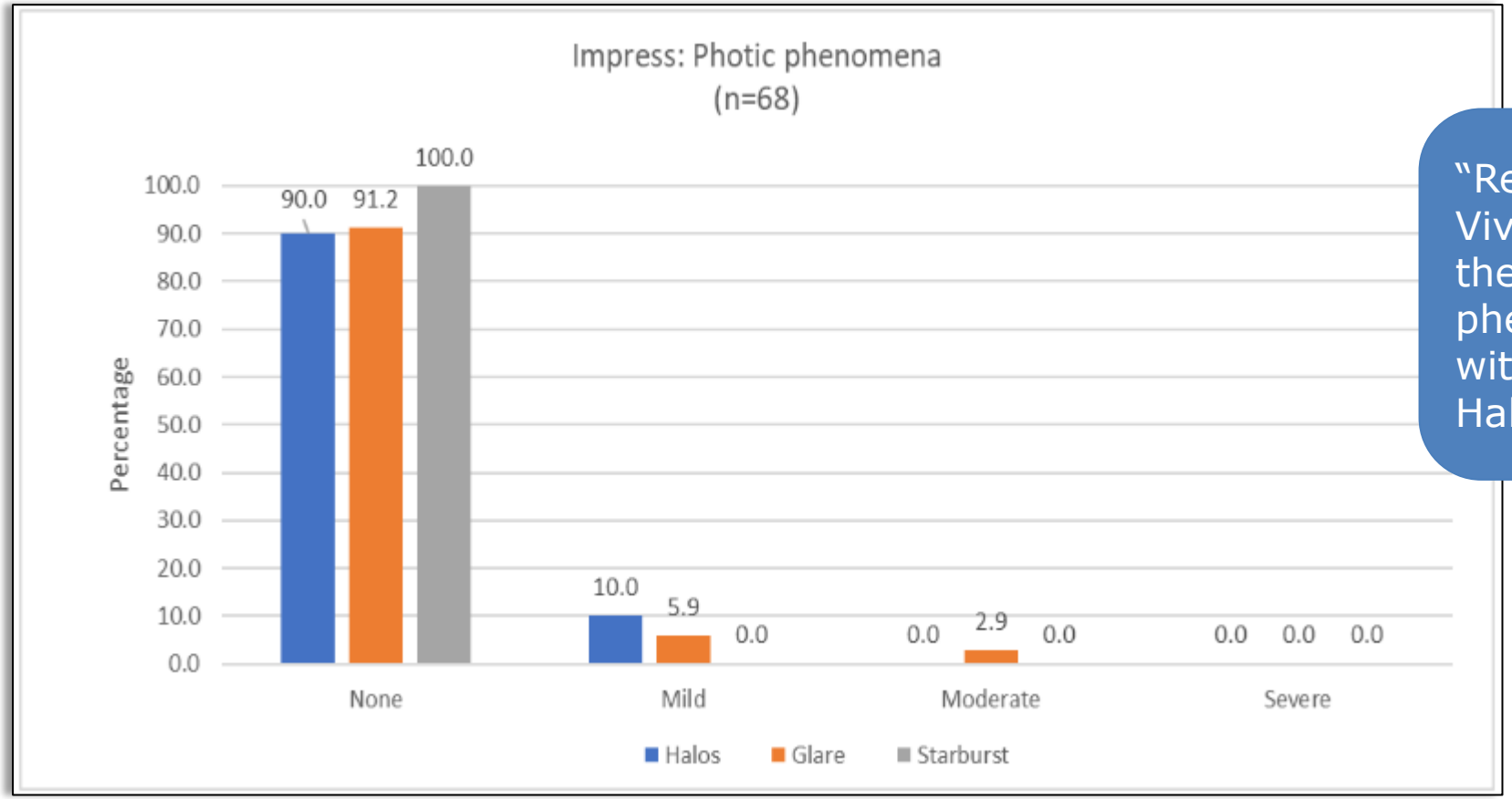
CLEARlog registry data
Vivinex Impress™ has a high intermediate spectacles independence rate at distance and intermediate



"Real world data" for Vivinex Impress™ underlines the increased spectacle independence with ~90% "never/some of the time" use glasses at intermediate distance.

Data as of July 2023

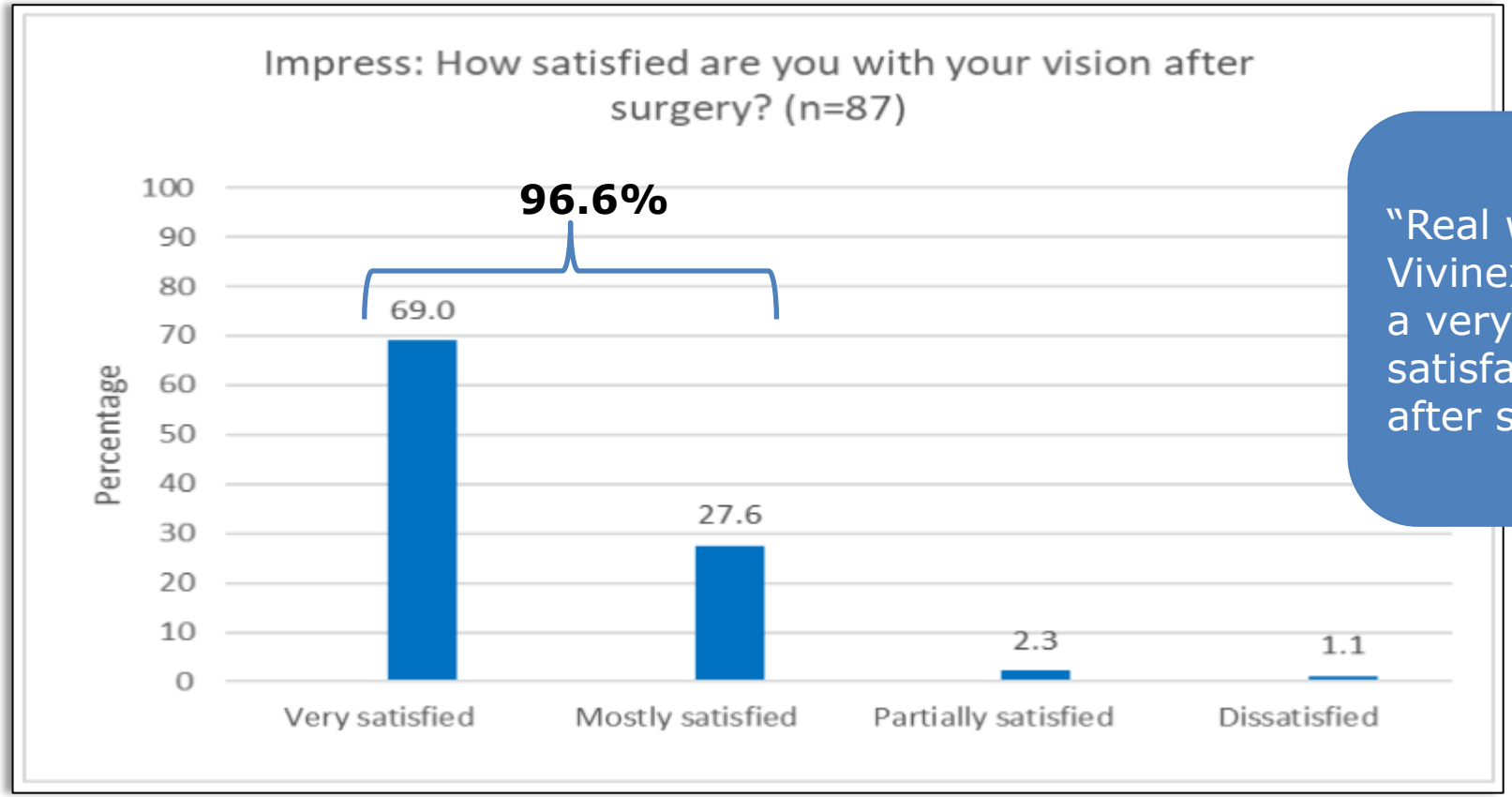
CLEARlog registry data
Vivinex Impress™ has NO “severe” photic phenomena



“Real world data” for Vivinex Impress™ confirms the absence of photic phenomena after surgery without any severe reports of Halos, Glare or Starburst.

Data as of July 2023

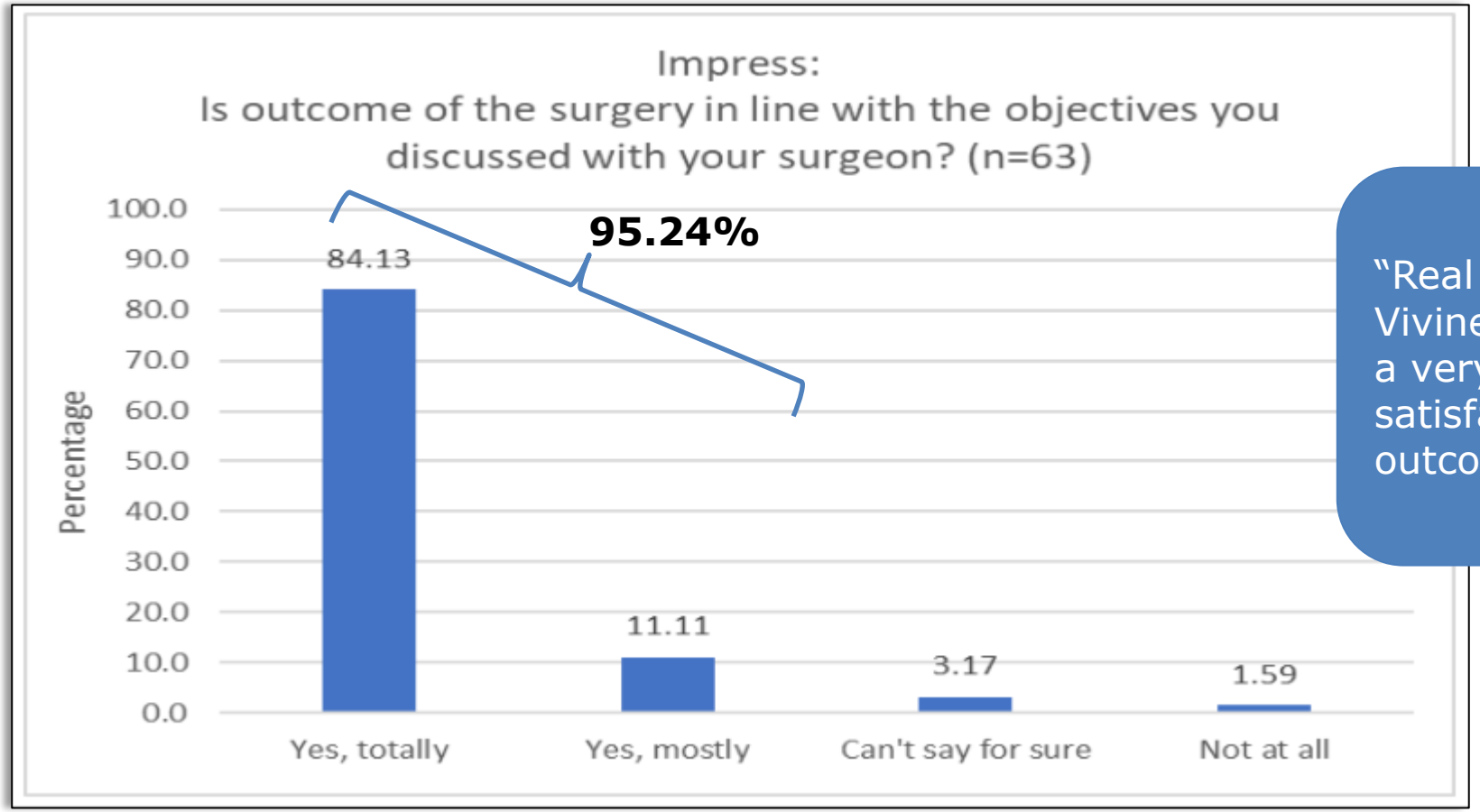
CLEARlog registry data
Vivinex Impress™ has a very high patient satisfaction rate



"Real world data" for Vivinex Impress™ confirms a very high patient satisfaction with the vision after surgery.

Data as of July 2023

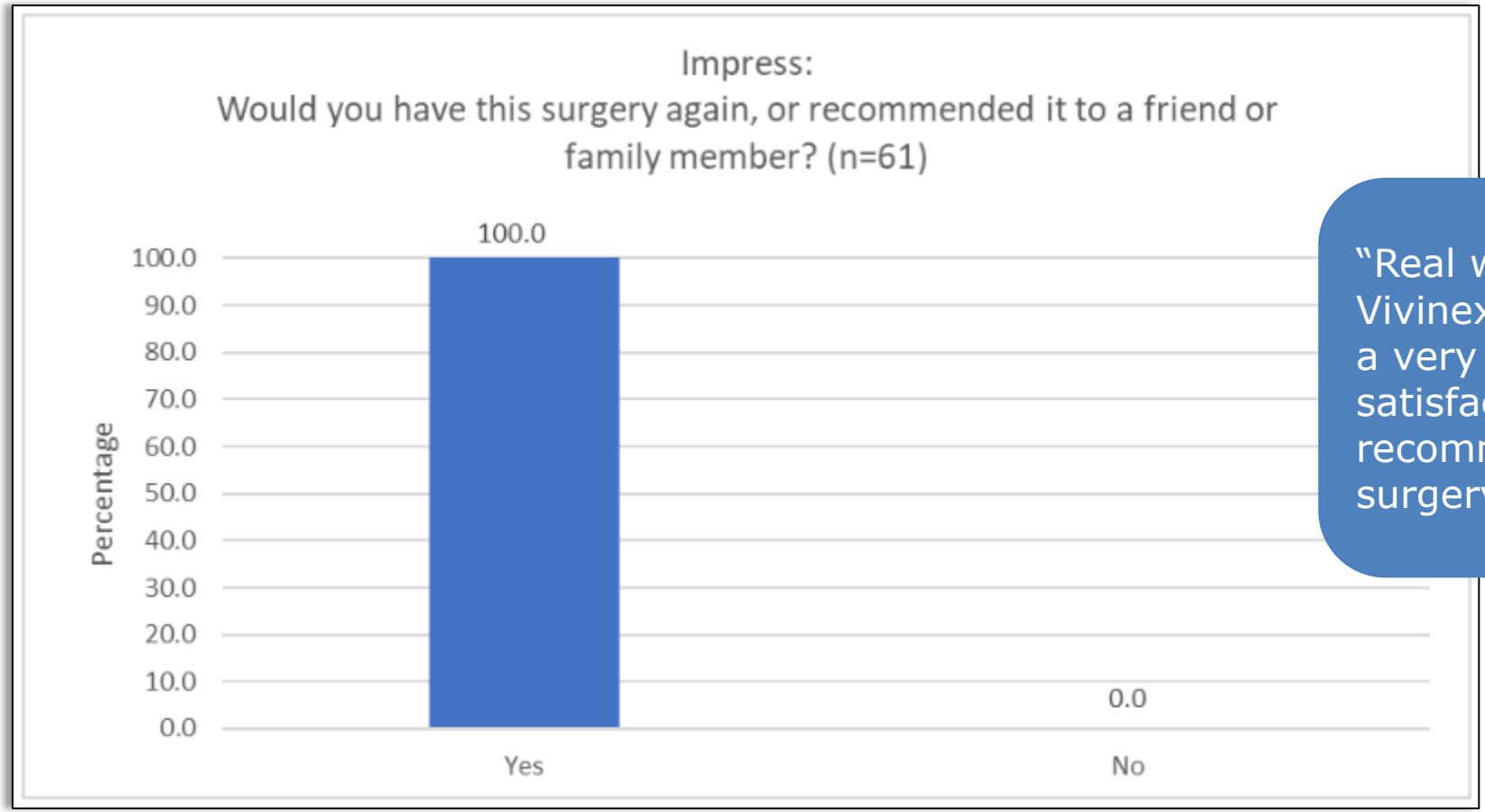
CLEARlog registry data
Vivinex Impress™ patient's outcomes are highly aligned with the objectives discussed with surgeons



"Real world data" for Vivinex Impress™ confirms a very high patient satisfaction with the outcome of surgery.

Data as of July 2023

CLEARlog registry data
Vivinex Impress™ - 100% recommendation rate



"Real world data" for Vivinex Impress™ confirms a very high patient satisfaction and recommendation rate after surgery.

Data as of July 2023

Vivinex Impress™ provides improved vision at intermediate distance, refractive predictability, and patient satisfaction

- Early clinical performance of Vivinex Impress™ is consistent with our theoretical estimations, aligning well with our positioning and the opportunity in the Enhanced Monofocal/"Best monofocal" segment

- Early COMP data is consistent with “Real world” CLEARlog registry results for Vivinex Impress™

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Positioning Statement: Vivinex Impress™

Statement capturing where the Vivinex Impress™ enhanced monofocal IOL is truly unique...

Surgeons can <u>trust</u> Vivinex Impress to set <u>a new benchmark for visual outcomes achieved by monofocal patients</u>

Reasons why/evidence sources:

1. ***"Trust" because…***
    1. *Robust study data behind visual outcome claims for…*
        - *Evidence: First COMP study results, first published clinical comparison from Italy and CLEARlog registry outcomes*
    2. *Robust clinical data supports the long term benefits of the Vivinex™ hydrophobic platform (glistening-free, proprietary aspheric design, active oxygen processing treatment, smooth surface, square optic edge)*
        - *Evidence: published studies about PCO, Glistenings, aspheric design, rotational stability/astigmatism correction*
    3. *The "Best in class" multiSert™ preloaded injector provides exceptionally smooth, **<u>consistent and predictable IOL delivery</u>** supporting OR efficiency in high volume cataract environments*
        - *Evidence: Usability study and Heidelberg publications*

2. ***"A new benchmark for the visual outcomes achieved by monofocal patients" because…***
    1. *Intermediate vision benefit with higher spectacle independence for a greater number of patients vs aspheric monofocal IOLs*
    2. *Excellent distance vision with no difference in best-corrected distance VA and contrast sensitivity vs aspheric monofocal IOLs*
    3. *No difference in visual disturbances vs aspheric monofocal IOLs*
        - *Evidence for all statements: First COMP study results*
    4. *Does not have the optical/material/injector downsides of competitor Enhanced Monofocal IOLs*

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NEW Campaign at ESCRS

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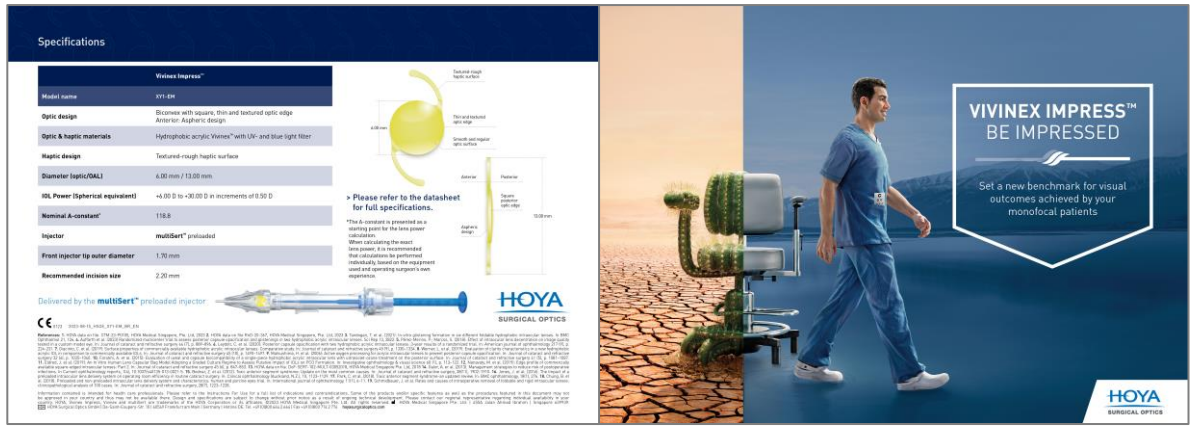
Introducing Vivinex Impress™ Brochure

RISE

TOWARDS NEW HEIGHTS



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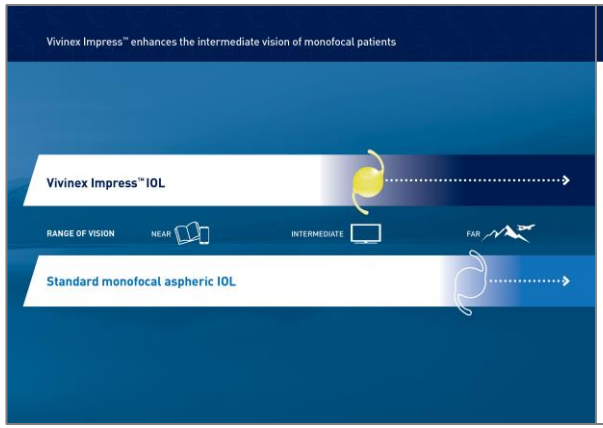

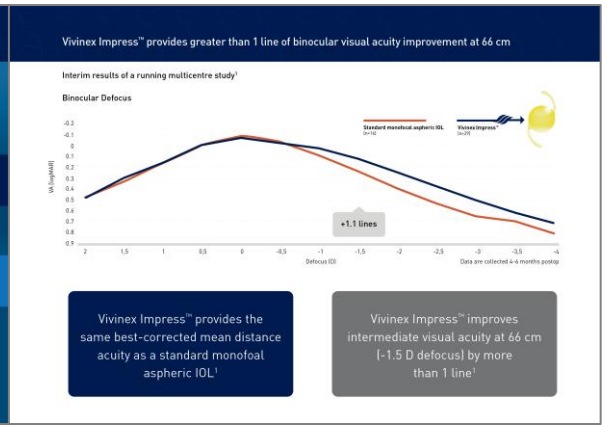

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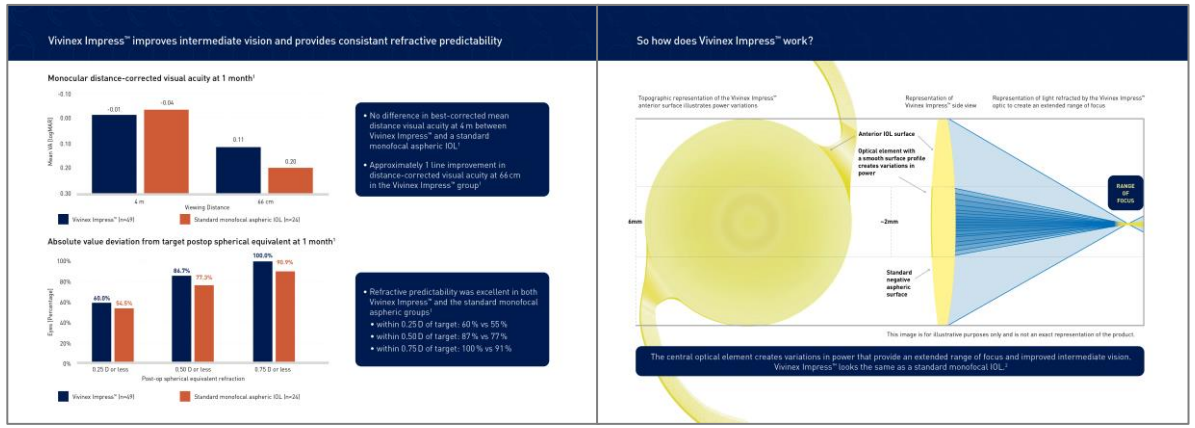

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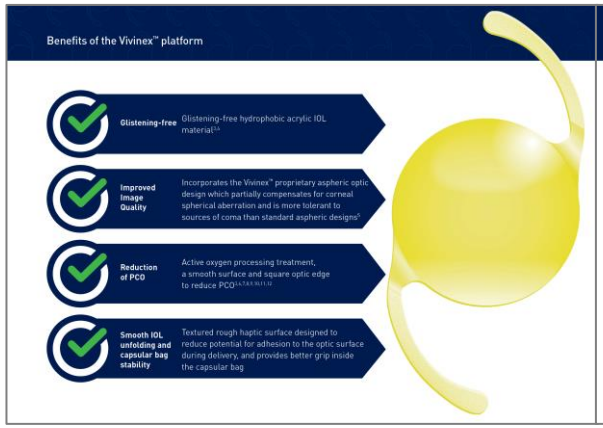

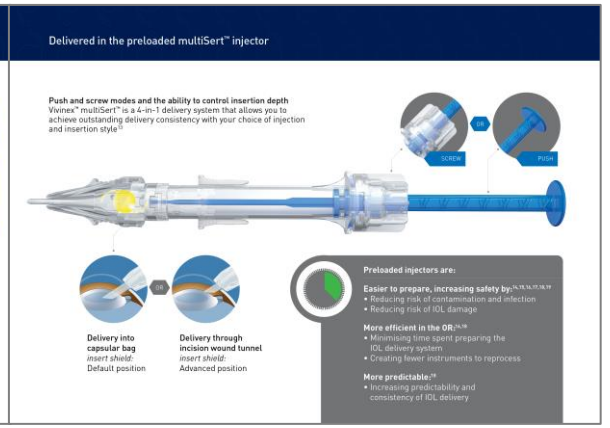

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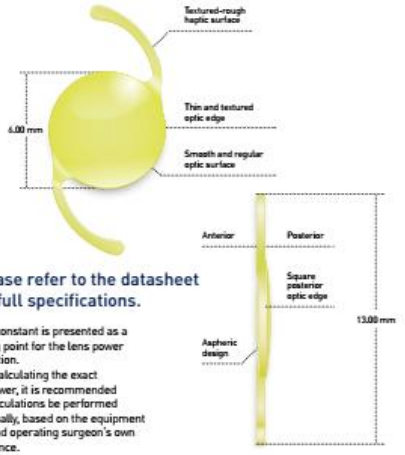
Vivinex Impress™ Brochure Storyflow: Focus on enhanced monofocal performance

Page 1

Specifications

	Vivinex Impress™
Model name	XY1-EM
Optic design	Biconvex with square, thin and textured optic edge Anterior: Aspheric 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
IOL Power (Spherical equivalent)	+6.00 D to +30.00 D in increments of 0.50 D
Nominal A-constant*	118.8
Injector	multiSert™ preloaded
Front injector tip outer diameter	1.70 mm
Recommended incision size	2.20 mm



> Please refer to the datasheet for full specifications.

*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.

Delivered by the **multiSert™** preloaded injector

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CE 0123 2023-08-15_HSOE_XY1-EM_BR_EN

References: 1. HOYA data on file. CTM-23-P0105, HOYA Medical Singapore, Pte. Ltd, 2023 2. HOYA data on file PnD-20-367, HOYA Medical Singapore, Pte. Ltd, 2023 3. Tandogan, T. et al. (2021): In-vitro clustering formation in six different foldable hydrophobic intraocular lenses. In: BMC Ophthalmol 21, 126. 4. Auffarth et al. (2023) Randomized multicenter trial to assess posterior capsule opacification and glistenings in two hydrophobic acrylic intraocular lenses. Sci Rep 13, 2022. 5. 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. 6. 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. 7. Giacinto, C. et al. (2019): Surface properties of commercially available hydrophobic acrylic intraocular lenses: Comparative study. In: Journal of cataract and refractive surgery 45 (9), p. 1330–1336. 8. Werner, L. et al. (2019): Evaluation of clarity characteristics in a new hydrophobic acrylic IOL in comparison to commercially available IOLs. In: Journal of cataract and refractive surgery 45 (10), p. 1490–1497. 9. Matsushima, H. et al. (2006): Active oxygen processing for acrylic intraocular lenses to prevent posterior capsule opacification. In: Journal of cataract and refractive surgery 32 (6), p. 1035–1040. 10. Faruhti, 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. 11. Eldred, J. et al. (2019): An In Vitro Human Lens Capsular Bag Model Adopting a Graded Culture Regime to Assess Putative Impact of IOLs on PCO Formation. In: Investigative ophthalmology & visual science 60 (1), p. 113–122. 12. Nanavaty, M. et al. (2019): Edge profile of commercially available square-edged intraocular lenses: Part 2. In: Journal of cataract and refractive surgery (5 (4), p. 847–853. 13. HOYA data on file. DoF-SERT-102-MULT-03052018, HOYA Medical Singapore Pte. Ltd, 2018 14. Gabor, A. et al. (2013). Management strategies to reduce risk of postoperative infections. In Current ophthalmology reports, 1(4), 10.1007/s40135-013-0021-5. 15. Bodner, Z. et al. (2012). Toxic anterior segment syndrome: Update on the most common causes. In: Journal of cataract and refractive surgery, 38(11), 1902–1910. 16. Jones, J. et al. (2016). The impact of a preloaded intraocular lens delivery system on operating room efficiency in routine cataract surgery. In: Clinical ophthalmology (Auckland, N.Z.), 10, 1123–1129. 17. Park, C. et al. (2018). Toxic anterior segment syndrome-an updated review. In: BMC ophthalmology, 18(1), 276. 18. Chung, B. et al. (2018). Preloaded and non-preloaded intraocular lens delivery system and characteristics: Human and porcine eyes trial. In: International journal of ophthalmology, 11(1), 6–11. 19. Schmidbauer, J. et al. Rates and causes of intraoperative removal of foldable and rigid intraocular lenses: clinicopathological analysis of 109 cases. In: Journal of cataract and refractive surgery, 28(7), 1223–1228.

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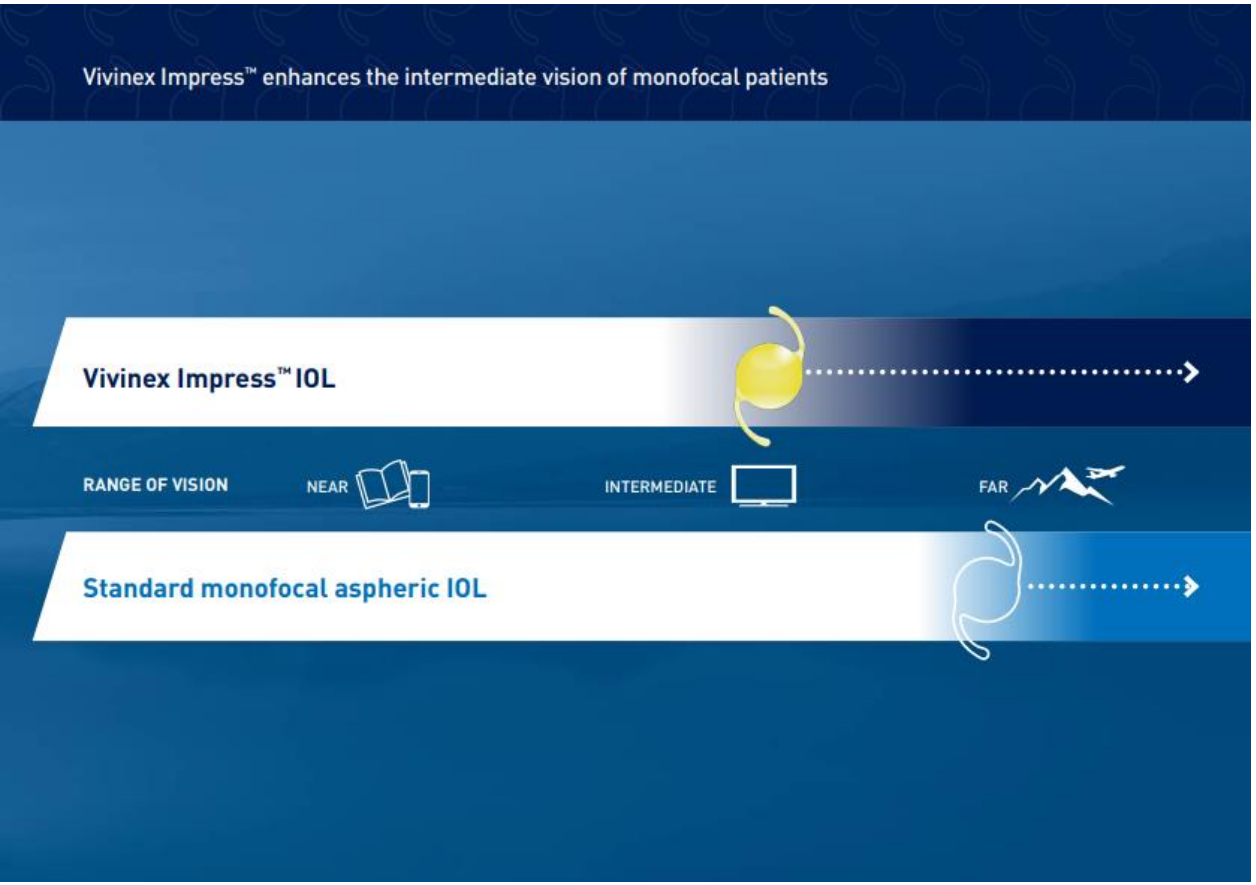
Vivinex Impress™ Brochure Storyflow: Focus on enhanced monofocal performance



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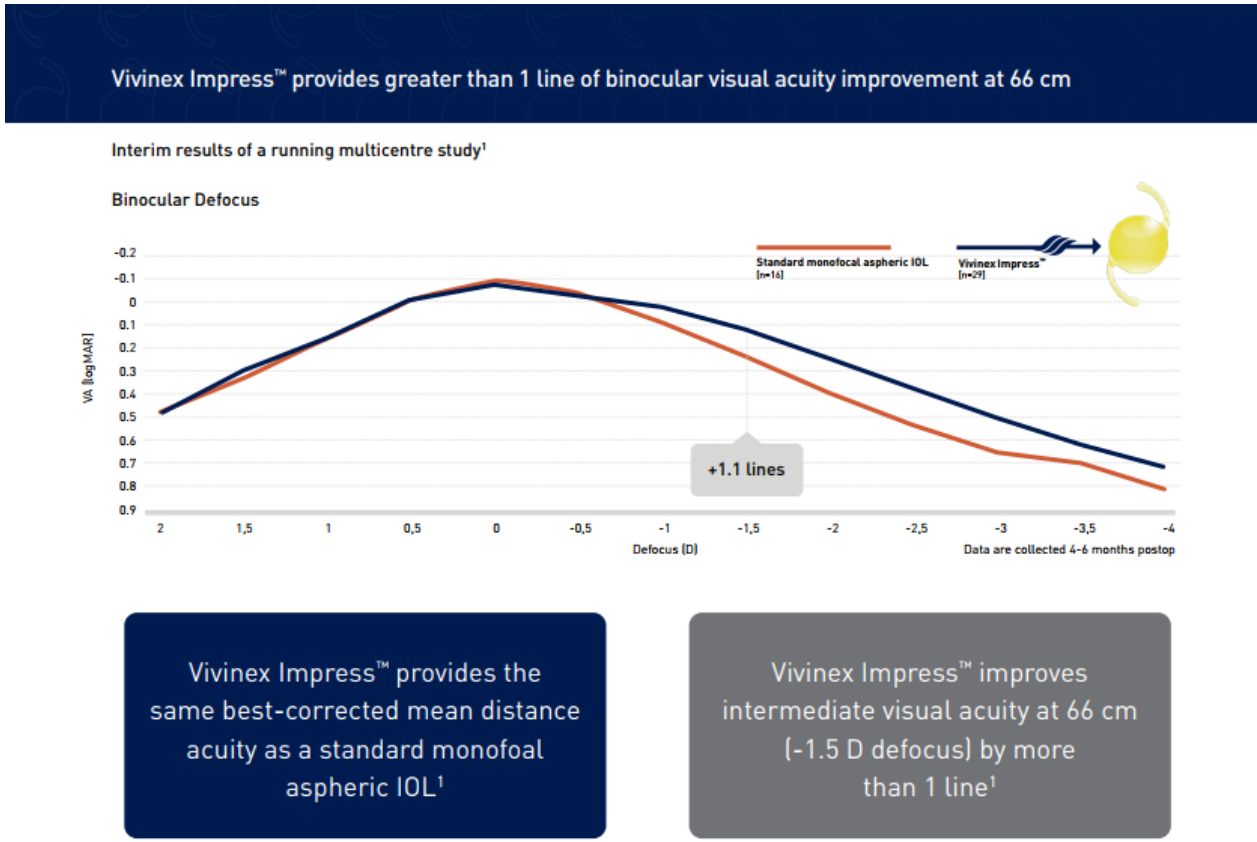

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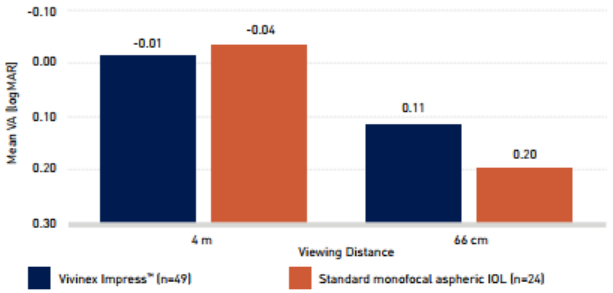
Vivinex Impress™ Brochure Storyflow: Focus on enhanced monofocal performance

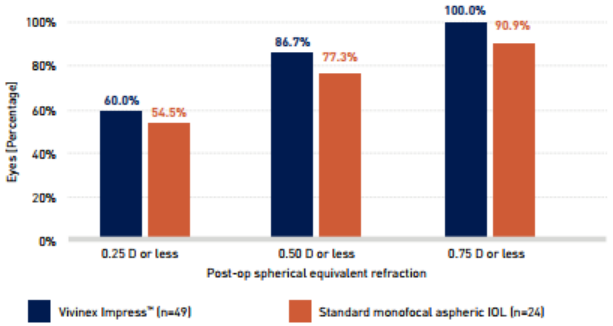
Vivinex Impress™ improves intermediate vision and provides consistant refractive predictability

Monocular distance-corrected visual acuity at 1 month[1]



- No difference in best-corrected mean distance visual acuity at 4 m between Vivinex Impress™ and a standard monofocal aspheric IOL[1]
- Approximately 1 line improvement in distance-corrected visual acuity at 66 cm in the Vivinex Impress™ group[1]

Absolute value deviation from target postop spherical equivalent at 1 month[1]



- Refractive predictability was excellent in both Vivinex Impress™ and the standard monofocal aspheric groups[1]
  - within 0.25 D of target: 60 % vs 55 %
  - within 0.50 D of target: 87 % vs 77 %
  - within 0.75 D of target: 100 % vs 91 %

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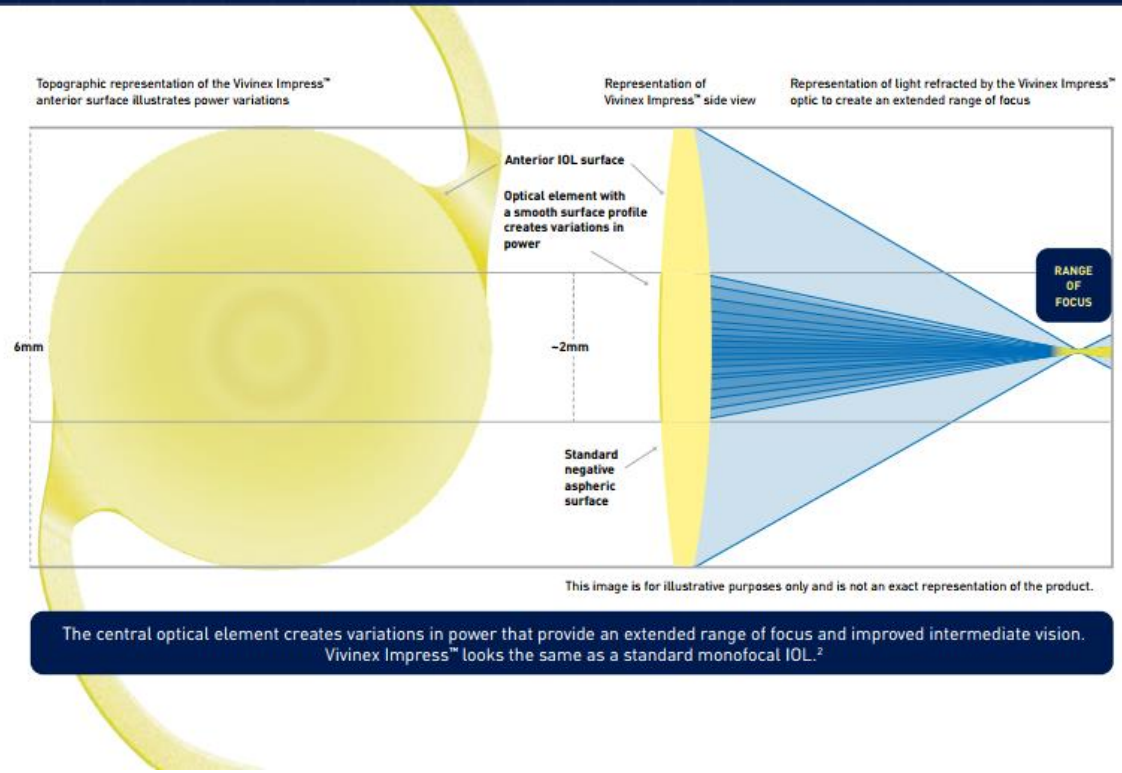
So how does Vivinex Impress™ work?



The central optical element creates variations in power that provide an extended range of focus and improved intermediate vision. Vivinex Impress™ looks the same as a standard monofocal IOL.[2]

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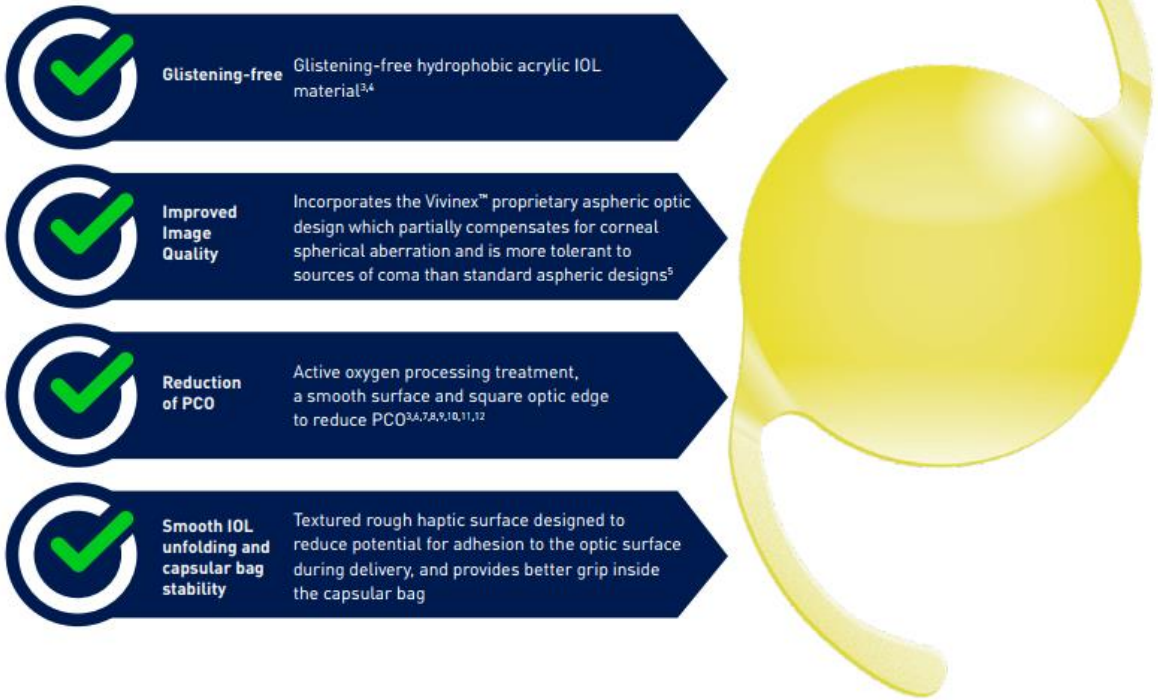
Vivinex Impress™ Brochure Storyflow: Focus on enhanced monofocal performance

Benefits of the Vivinex™ platform



Glistening-free — Glistening-free hydrophobic acrylic IOL material[3,4]

Improved Image Quality — Incorporates the Vivinex™ proprietary aspheric optic design which partially compensates for corneal spherical aberration and is more tolerant to sources of coma than standard aspheric designs[5]

Reduction of PCO — Active oxygen processing treatment, a smooth surface and square optic edge to reduce PCO[3,6,7,8,9,10,11,12]

Smooth IOL unfolding and capsular bag stability — Textured rough haptic surface designed to reduce potential for adhesion to the optic surface during delivery, and provides better grip inside the capsular bag

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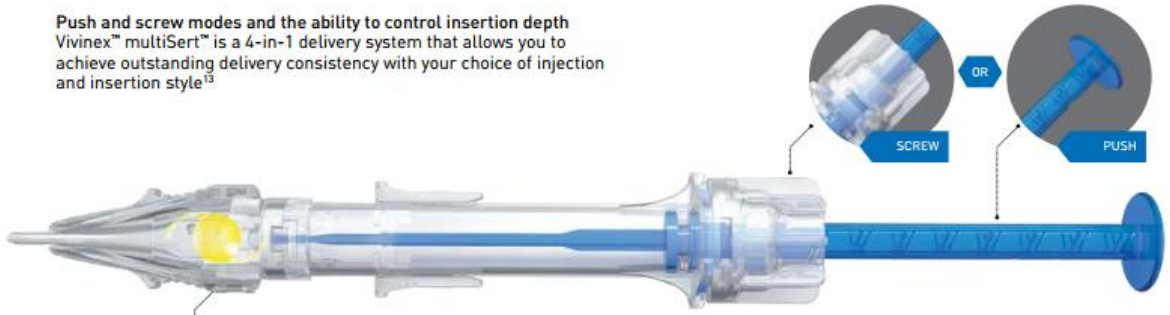
Delivered in the preloaded multiSert™ injector

Push and screw modes and the ability to control insertion depth
Vivinex™ multiSert™ is a 4-in-1 delivery system that allows you to achieve outstanding delivery consistency with your choice of injection and insertion style[13]



Delivery into capsular bag
insert shield:
Default position

Delivery through incision wound tunnel
insert shield:
Advanced position

Preloaded injectors are:

Easier to prepare, increasing safety by:[14,15,16,17,18,19]
- Reducing risk of contamination and infection
- Reducing risk of IOL damage

More efficient in the OR:[14,18]
- Minimising time spent preparing the IOL delivery system
- Creating fewer instruments to reprocess

More predictable:[18]
- Increasing predictability and consistency of IOL delivery

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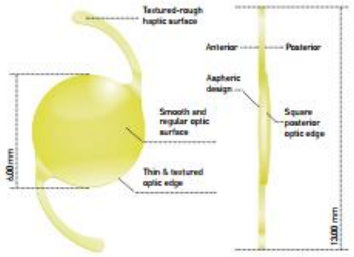
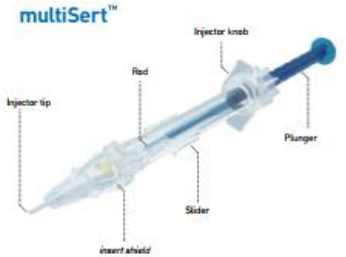
Vivinex Impress™ Datasheet

Datasheet — MODEL XY1-EM





	Vivinex Impress™			
Model name	XY1-EM			
Optic design	Biconvex with square, thin and textured optic edge Anterior: Aspheric 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			
IOL power (Spherical equivalent)	+6.00 D to +30.00 D in increments of 0.50 D			
Nominal A-constant*	118.8			
Optimized constants**	Haigis	a_0 = -1.0459	a_1 = 0.2547	a_2 = 0.2291
	Hoffer Q	pACD = 5.700		
	Holladay 1	sf = 1.928		
	SRK/T	A = 119.193		
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.

** These optimized constants for the calculation of intraocular lens power published by IOLCon on their website: https://iolcon.org are calculated from 2,857 clinical results for Vivinex™ Model XY1+SP/XC1+SP as of August 15, 2023. 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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HOYA SURGICAL OPTICS

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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Optimized constants for Vivinex Impress

— New optimized constants to be highlighted for Vivinex monofocal, which are also valid for Vivinex Impress

Nominal A-constant*	118.8			
Optimized constants**	Haigis	a_0 = -1.0459	a_1 = 0.2547	a_2 = 0.2291
	Hoffer Q	pACD = 5.700		
	Holladay 1	sf = 1.928		
	SRK/T	A = 119.193		

* 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.

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Thank you for your attention!

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Dr Camille Bosc
Nantes (France)

Dr Ségolène Roemer
Lausanne (Switzerland)

Dr Michael Janusz Koss
Munich (Germany)

Dra. Rodríguez
Villacé (Spain)

Dr Amit Gupta
Jaipur (India)

Dr Rachid Tahiri
Granville (France)

Dr. Fabio D'Arrigo
Messina (Italy)

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