

Take advantage, use **Advanced**

enova
Advanced[®]

Preloaded Extended Depth of Focus (EDOF) IOL



Enova Advanced[®] Non-Diffractive Hydrophobic EDOF IOL



Our new A-class product - The Enova Advanced[®] non-diffractive EDOF IOL Available on our hydrophobic material platform - Enova[®].

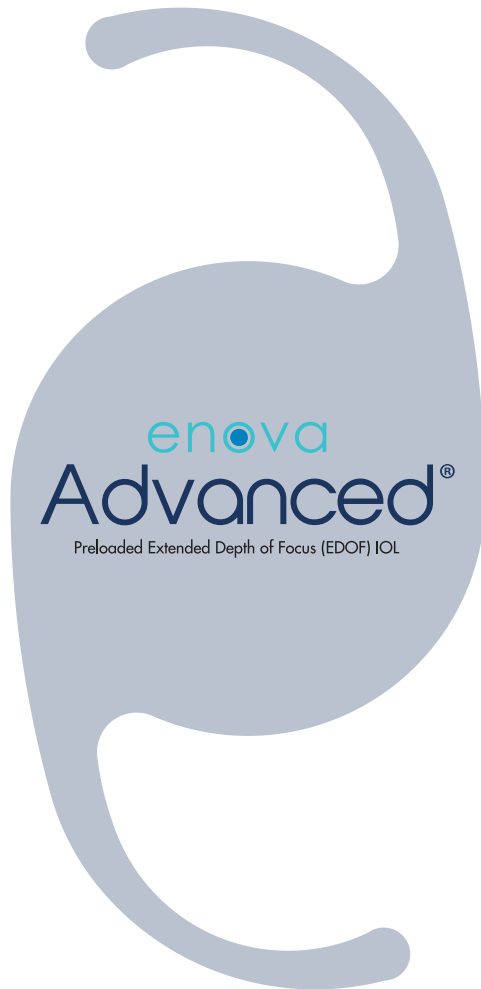
Non-diffractive “Light Tailoring Technology” providing:

- Excellent visual acuity for far vision.
- Great visual acuity for intermediate vision reaching into near vision zone.
- Monofocal-like halo and glare profile.

Launched on next generation hydrophobic Enova[®] IOL material platform combining:

- 100% glistening-free.
- Dry-packed.
- Controlled unfolding even in operating room temperature settings.

Take advantage, use Advanced



Sharp
Far Vision¹



Strong
Intermediate Vision¹



Near
Vision Effect¹



Monofocal-like
Halo and Glare Profile¹



100%
Glistening-Free Material²



Pre-Conditioning
Free³



Preloaded



1.Data on file. Medical Report MR_EA_230605. VSY Biotechnology Laboratories. 06.2023.

2.Data on file. L. Werner et. al. In vitro study evaluating the tendency of different intraocular lenses to form intraoptical glistenings. Study report. RDR_EGF3_05072020. Utah, USA 07.2020.

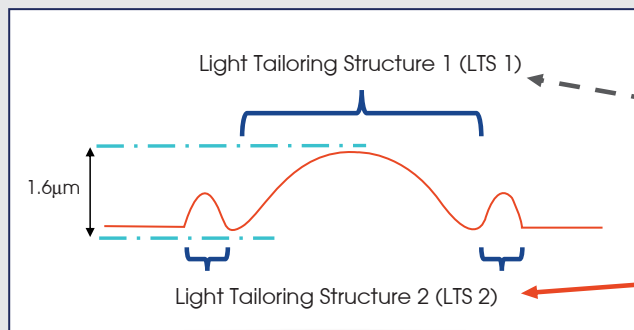
3.Data on file. Technical Report TR_EA_200511. VSY Biotechnology Laboratories. 05.2020

Light Tailoring Technology

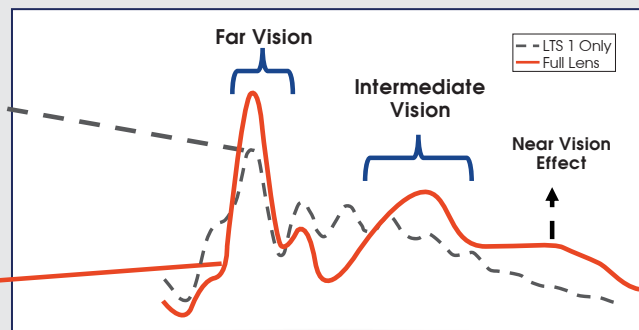
Discover VSY Biotechnology's groundbreaking "Light tailoring technology" for exceptional optical performance even in challenging lighting conditions. Experience the new A-class product, the non-diffractive Enova Advanced® EDOF IOL.

Light Tailoring Technology

The unique Light Tailoring Technology uses two structures (LTS 1 and 2) placed in the central 2 mm aperture to broaden and fine-tune the provided light.



- LTS 1 widens and distributes light beyond the far focus into intermediate and near vision ranges.
- LTS 2 Fine-tunes light for a more refined intermediate visual acuity and basic near visual acuity.

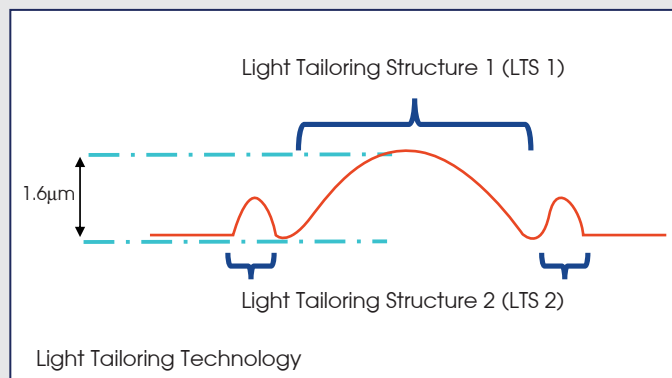


- LTS 1 distributes light broadly for EDOF.
- LTS 2 Fine-tunes the light distribution to strengthen the relevant distances (far, intermediate and basic near).

Light Tailoring Technology

"Light tailoring technology" delivers outstanding distance vision in photopic, mesopic, and scotopic light conditions along with excellent intermediate vision.

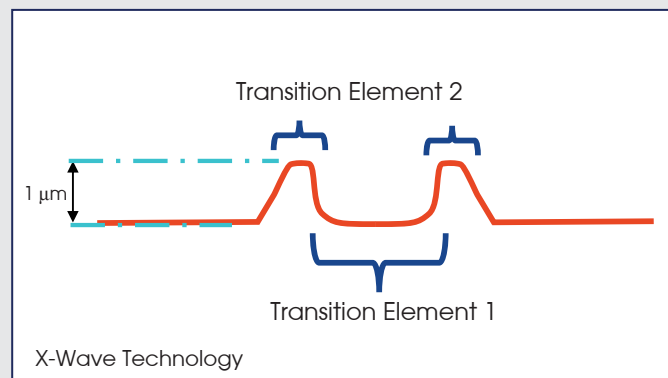
ENOVA ADVANCED®



Light Tailoring Technology Working Principle

- Light Tailoring Structure 1 provides a broader far and intermediate distribution of light energy.
- Light Tailoring Structure 2 improves the light distribution for "tailor-made" visual acuity for far, intermediate, and basic near vision.
- Enova Advanced® has a minimal spherical aberration design thanks to its light tailoring structure.

AcrySof VIVITY®



X-Wave Technology Working Principle

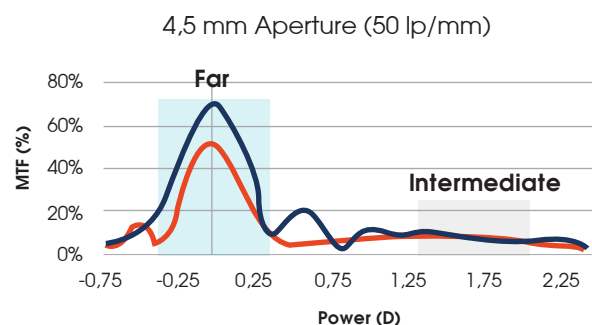
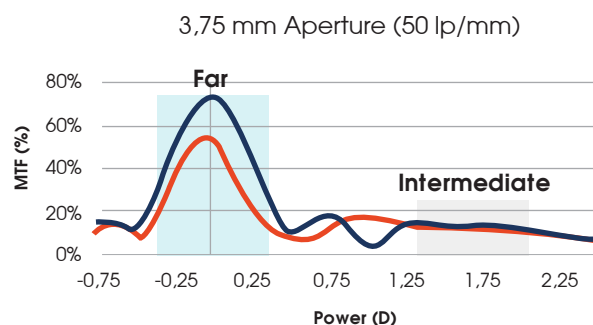
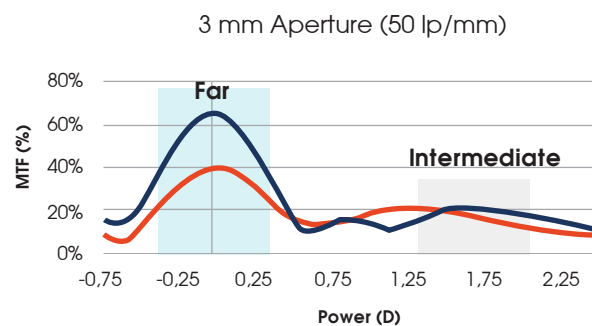
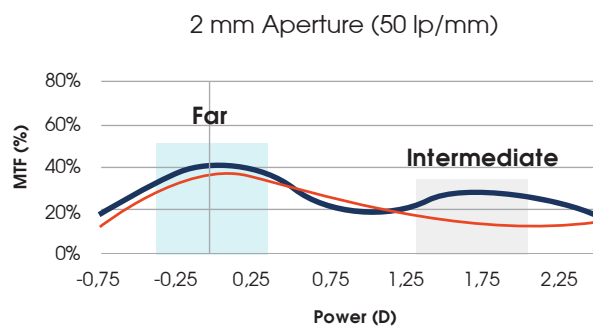
- Transition Element 1 stretches the light for EDOF.*
- Transition Element 2 shifts the wavefront for maximum energy usage.*

*Tognetto, Daniele, et al. "Profile of a new extended range-of-vision IOL: a laboratory study." Graefes Archive for Clinical and Experimental Ophthalmology (2022): 1-4.
 Ferrando, Vicente, et al. "Profile of a new extended range-of-vision IOL: comments on the laboratory study by Tognetto et al." Graefes Archive for Clinical and Experimental Ophthalmology 260.12 (2022): 4021-4022.

Optical Benchmark Results

Enova Advanced® vs. AcrySof Vivity®

Enova Advanced® distributes more light energy to the far vision and thus shows higher modulation transfer function (MTF) values compared to AcrySof Vivity®.



— Enova Advanced® — AcrySof Vivity®

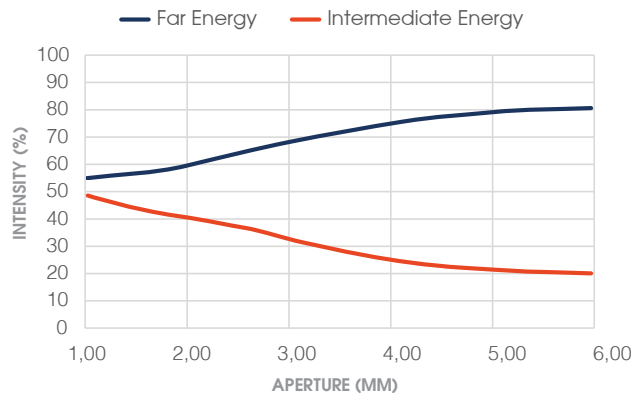
Measurement Equipment: Lambda PMTF device (Belgium) / In house measurement. Eye Model: ISO Eye Model / with minimal spherical aberration.
Samples: Advanced and Vivity lenses with 21 D. Measurement Date: 06.2023

Optical Benchmark Results

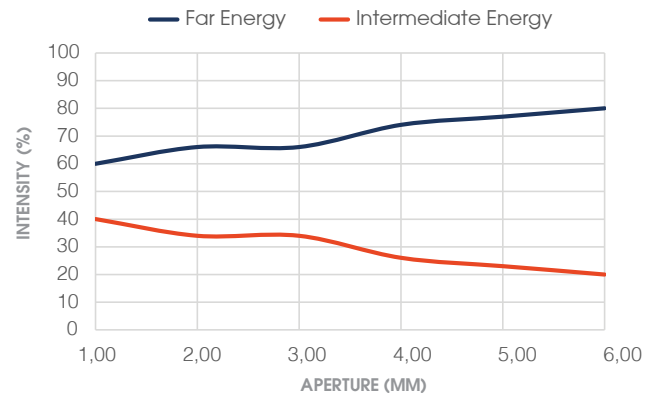
Enova Advanced® vs. AcrySof Vivity®

Enova Advanced® has a higher focus on the far foci and thus providing excellent visual acuity even in challenging lighting conditions.

ENOVA ADVANCED® ENERGY DISTRIBUTION



ALCON VIVITY® ENERGY DISTRIBUTION

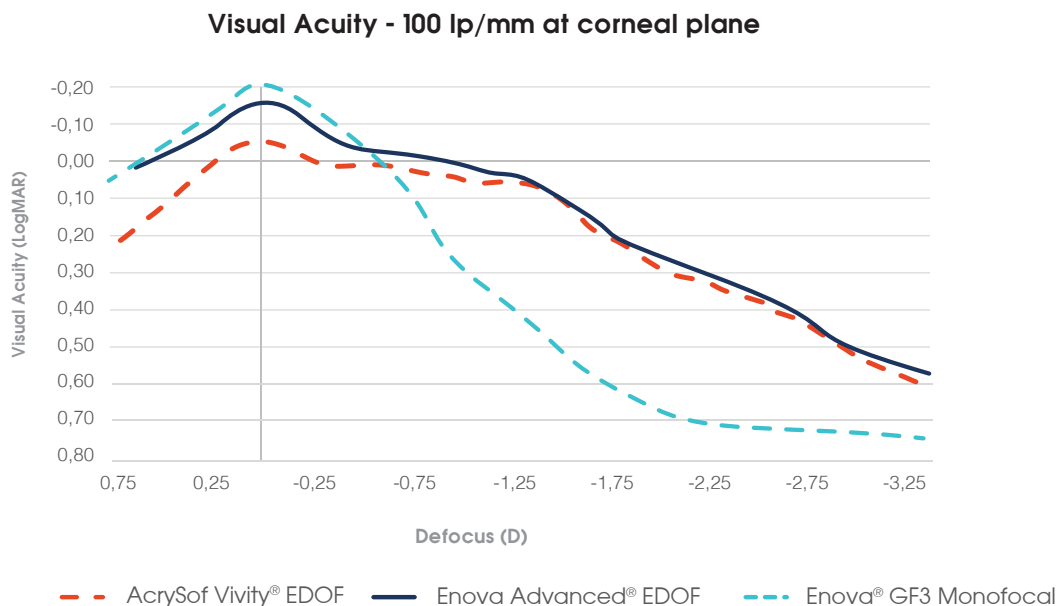


Measurement Equipment: Lambda PMTF device (Belgium) / In house measurement. Eye Model: ISO Eye Model / with minimal spherical aberration.
Samples: Advanced and Vivity lenses with 21 D. Measurement Date: 06.2023

Theoretical Defocus Curve Comparison

Enova Advanced® EDOF vs. AcrySof Vivity® EDOF vs. Enova® GF3 Monofocal

Compared to AcrySof Vivity®, the theoretical defocus curve values demonstrate excellent far vision without deficiencies in the intermediate range.



Measurement Equipment: Theoretically derived from inhouse MTF measurements (1).

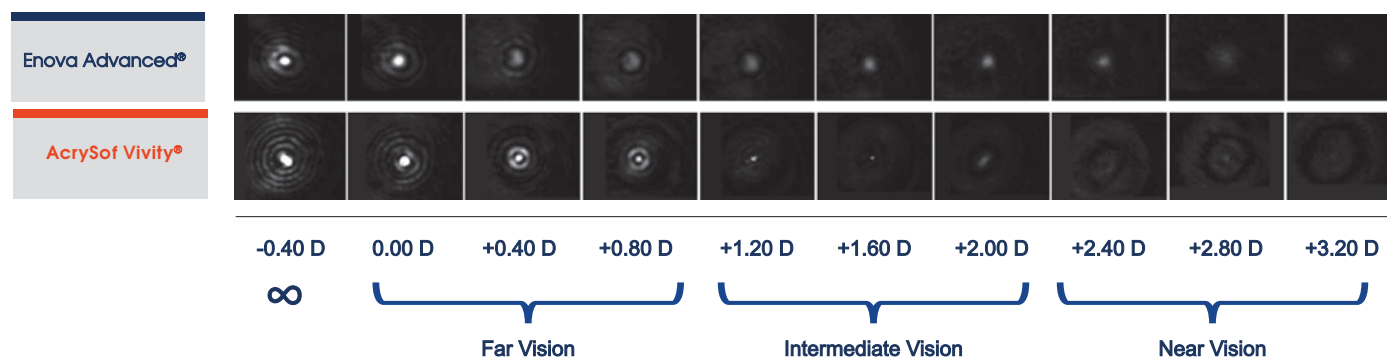
Samples: ENOVA GF3, Advanced and Vivity lenses with 21 D.

Measurement Date: 06.2023

(1) Alarcon, A., Canovas, C., Rosen, R., Weeber, H., Tsai, L., Hileman, K., & Piers, P. (2016). Preclinical metrics to predict through-focus visual acuity for pseudophakic patients. Biomedical Optics Express, 7(5), 1877. <https://doi.org/10.1364/BOE.7.001877>

Enova Advanced® vs. Alcon AcrySof Vivity® PSF Measurements

The Enova Advanced® has less Halo & Glare compared to AcrySof Vivity® according to the in-vitro lab measurements performed on a bench setup constructed specifically to assess PSF (1).



Measurement Equipment: Inhouse optic benchmark setup (1).

Samples: Advanced and Vivity lenses with 21 D.

Measurement Date: 08.2023

(1) Sievers J, Elsner R, Bohn S, Schünemann M, Stolz H, Guthoff RF, Stachs O, Sperlich K. Method for the generation and visualization of cross-sectional images of three-dimensional point spread functions for rotationally symmetric intraocular lenses. Biomed Opt Express. 2022 Feb 1;13(2):1087-1101. doi: 10.1364/BOE.446869. PMID: 35284182; PMCID: PMC8884235.

USAF Target Images Enova Advanced® vs. AcrySof Vivity®

Far

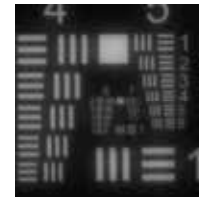
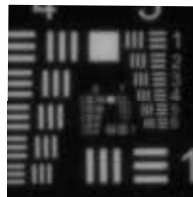
Enova Advanced®

AcrySof Vivity®

PHOTOPIC



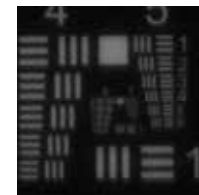
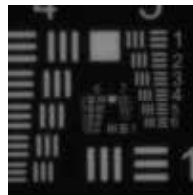
3 mm



MESOPIC



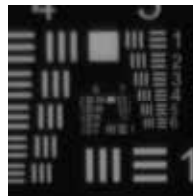
3.75mm



SCOTOPIC



4.5mm



Measurement Equipment: Lambda PMTF device (Belgium) / In house measurement. Eye Model: ISO Eye Model / with minimal spherical aberration.

 Samples: Advanced and Vivity lenses with 21 D. Measurement Date: 06.2023

USAF Target Images Enova Advanced® vs. AcrySof Vivity®

Intermediate

PHOTOPIC



3 mm

Enova Advanced®



AcrySof Vivity®



Measurement Equipment: Lambda PMTF device (Belgium) / In house measurement. Eye Model: ISO Eye Model / with minimal spherical aberration.
Samples: Advanced and Vivity lenses with 21 D. Measurement Date: 06.2023

Enovation of 100% Glistening-Free IOL Material

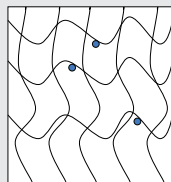
The Enova Advanced® IOL Material is the first 100% Glistening-Free hydrophobic acrylic IOL that does not require pre-hydration and storage in saline solution!

The Enova Advanced® EDOF IOL is dry-packed and boasts exceptional optical and mechanical properties.

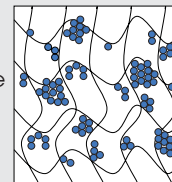
Glistening Formation in IOL

Water molecules bind to certain chemical groups through weak hydrogen bonds. Over time, more water molecules diffuse into the polymer network and bind preferably to other water molecules, which forms clusters referred to as "glistening."

First day of
implementation



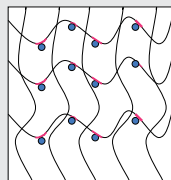
One year after the
implementation



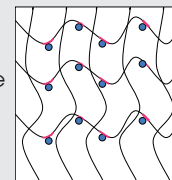
ENOVA® 100% Glistening-Free IOL

The unique composition of Enova Advanced® material allows the uniform hydration of specific sites, controlled water uptake, and resistance to glistening formation.

First day of
implementation



One year after the
implementation



100%

unique hydrophobic
IOL material

in-house production

100% Glistening-Free IOL Material

Conclusion by the University of Utah



In vitro glistenings study: University of Utah

Study: *In vitro study evaluating the incidence of different intraocular lenses*

to form intraocular glistenings

STUDY REPORT

Intermountain Ocular Research Center
Julia A. Messer Eye Center
University of Utah

Sponsor: VSY Biotechnology



In vitro glistenings study: University of Utah

Conclusions: Enova® hydrophobic acrylic intraocular lenses exhibited no glistening formation after hydration and variation of the temperature. Tecnis intraocular lenses exhibited trace glistening formation, and AcrySof intraocular lenses exhibited mild glistening formation in these in vitro test conditions. The new Enova® intraocular lenses showed no surface haze and glistenings when compared with other commercially available hydrophobic acrylic IOLs as AcrySof and Tecnis intraocular lenses.

Liliana Werner, MD, PhD

Nick Mamalis, MD

Liliana Werner
Nick Mamalis

Week 1: The findings at this time point were generally similar to those on Day 1. Overall, whenever glistening formation was observed in this study at week 1, it was mostly within the central 4.0 mm of the IOL optic.

- Enova® IOLs: No glistening, no haze.
- AcrySof IQ IOLs: Mild optic haze (giving the lens a slight yellowish/brownish discoloration under light microscopy) and mild glistening formation. Diameter of the glistenings: 10 to 20 microns.
- Tecnis IOLs: Moderate central optic haze (giving the central part of the optic a yellowish/brownish discoloration under light microscopy) and trace glistening formation. Diameter of glistenings: 25 microns.

In an attempt to quantify glistening formation within the lenses, the number of glistenings or microvacuoles (MV) that were well focused in the X200 light photomicrographs (area of 0.35 mm²) were counted, and the results were converted to MV/mm².

IOL	MV/mm² Week 1
Enova®	0
AcrySof IQ	8.7
Tecnis	2.9

Table 1 : Number of Microvacuoles Converted to MV/mm²



In vitro glistenings study: University of Utah

Conclusions: Enova® hydrophobic acrylic intraocular lenses exhibited no glistening formation after hydration and variation of the temperature. Tecnis intraocular lenses exhibited trace glistening formation, and AcrySof intraocular lenses exhibited mild glistening formation in these in vitro test conditions. The new Enova® intraocular lenses showed no surface haze and glistenings when compared with other commercially available hydrophobic acrylic IOLs as AcrySof and Tecnis intraocular lenses.

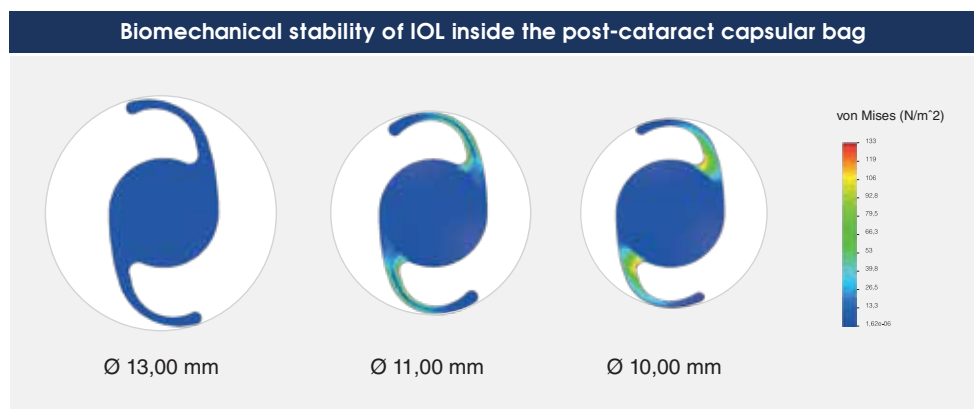
Liliana Werner, MD, PhD

Nick Mamalis, MD

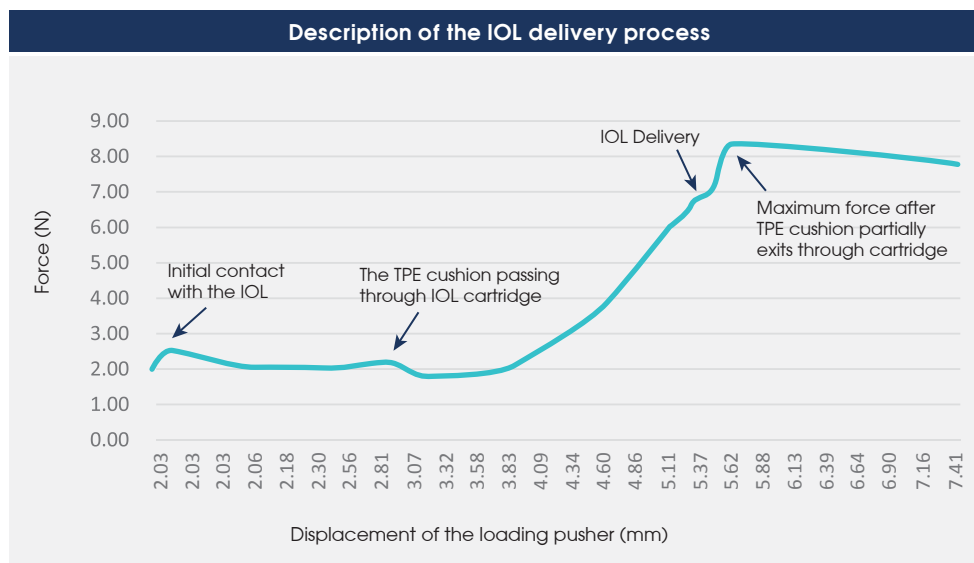
Liliana Werner
Nick Mamalis

Outstanding Biomechanical Properties

Gentle and controlled unfolding process in the posterior chamber and no pre-warming or special pre-conditioning is required.



Introducing our groundbreaking IOL, delivering easy unfolding, special haptic design and IOL memory effect for great stability, and smooth injection capability.



Experience the convenience of controlled deployment for precise positioning and a seamless implantation process.

No Pre-Conditioning Required

A polymer's Glass Transition Temperature (T_g) is reached when the polymer changes from a rigid material to a soft material. Having a T_g of -2.0°C , all IOLs with the unique Enova® material undergo a gentle and controlled unfolding process below standard operating room temperatures.

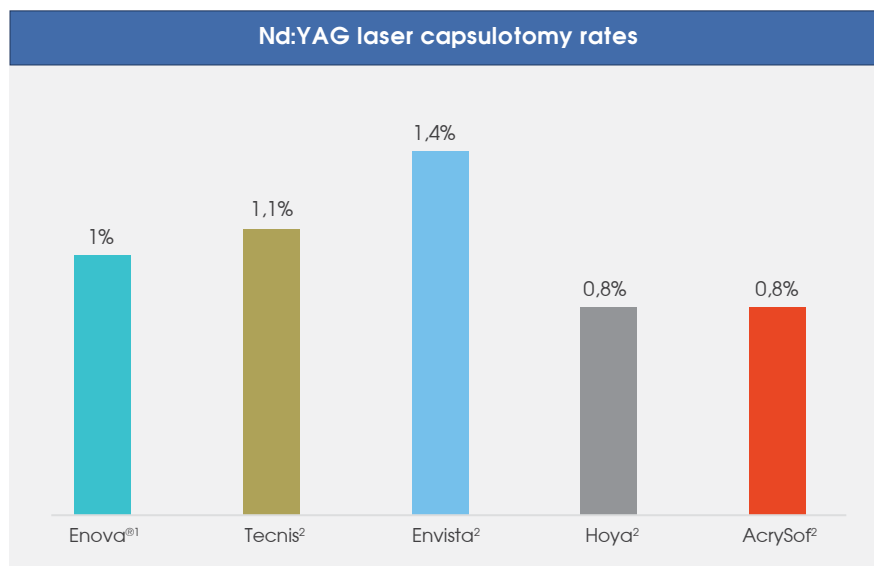
Thus, no warming or special pre-conditioning is required.

IOL	T_g ($^{\circ}\text{C}$)	Glistening	Packaging State
enova®	-2.0	No	Dry
AcrySof Vivity®	15	Yes	Dry
Tecnis®	14	Yes	Dry

Clinically Proven Low PCO Rate

Posterior capsule opacification (PCO) after cataract surgery is impacted by the intraocular lens' (IOL) design and material. Enova Advanced®'s new 100% Glistening-Free material minimizes the risk of PCO and Nd: YAG procedures after implantation.

In the multicenter studies performed on Enova Advanced® IOLs, PCO was evaluated on 320 eyes. After 1 year, the post-operative results showed that only 5% of the total eyes and 1% of total implantations had PCO, necessitating Nd-YAG laser treatment.



1- VSY Biotechnology Data on File, 2023.

2- RCOphth National Ophthalmology Database Audit Feasibility Study of Post-cataract Posterior Capsule Opacification 2021

Ready-to-Go Preloaded System

Due to its patented Rotaryjet technology, the Enova Advanced® Hydrophobic IOL with the Rotaryjet Preloaded IOL system provides a safe, efficient, and user-friendly delivery procedure. Its smart design allows for reliable surgery with smooth IOL implantation and reduced post-op risks.

Step 1

Apply BSS, followed by the OVD. The IOL must be implanted within one hour.

Step 2

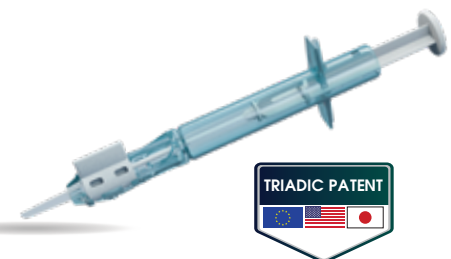
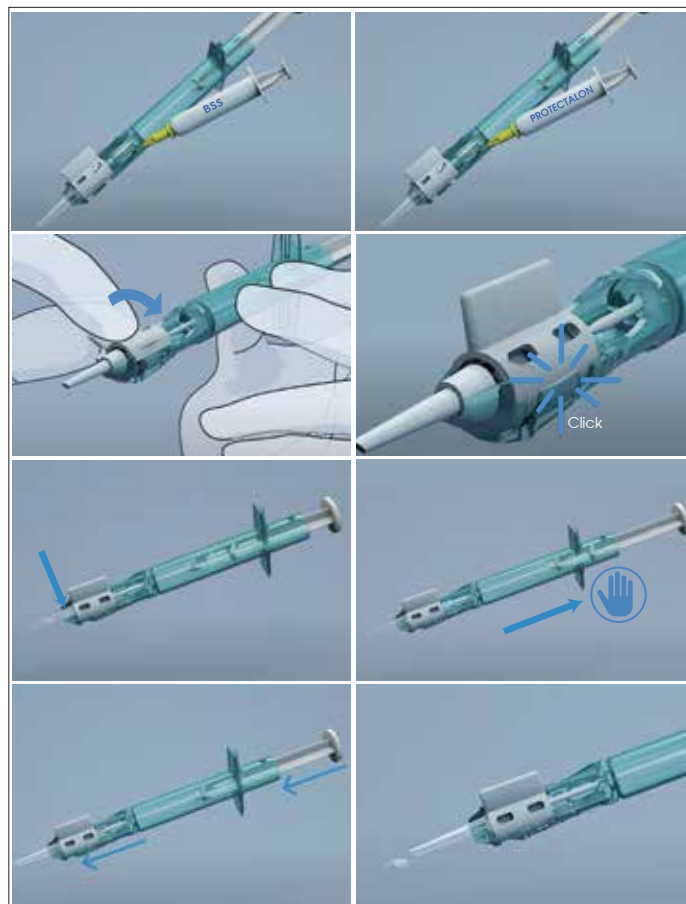
Rotate the mechanism through 90 degrees until you hear the 'click'.

Step 3

Push the injector until the blue cushion is visible through the cartridge. Then, pull it back gently until it is automatically stopped by the barrier.

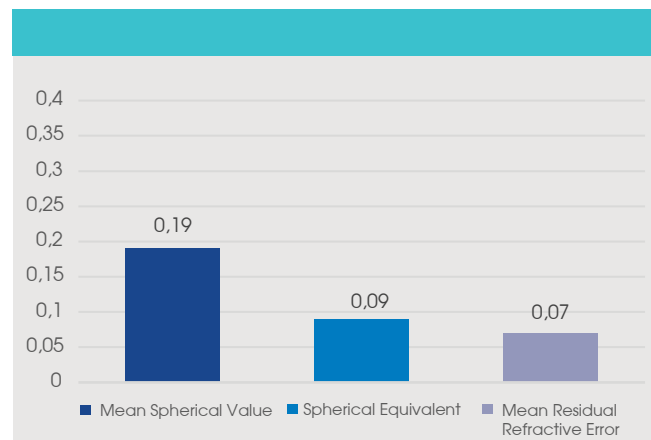
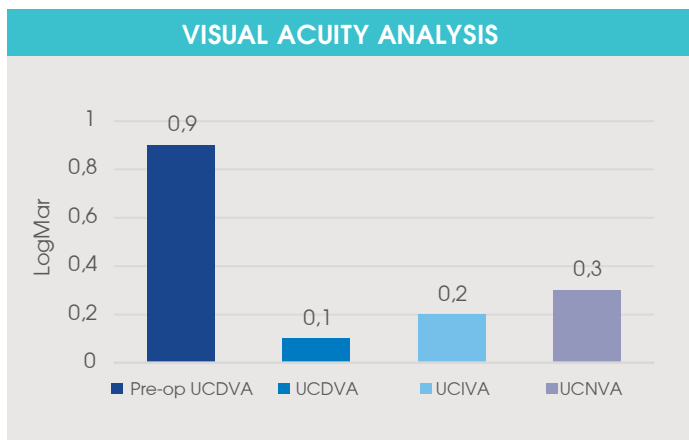
Step 4

Now it is ready to inject.



Early Multi-Center Clinical Results

Number of eyes n=92
Number of patients n=63



Conclusion

The first post-operative visual acuity results are extremely positive regarding the far and intermediate vision and even basic reading capabilities when it comes to the near vision.

Refractive errors were in an acceptable range of -0.50 D and +0.50 D. No glistening was observed.

IOL Centralization is very good. No decentralization and tilt were observed.

No adverse event was reported. Early patient satisfaction rates were excellent.

Technical Features

Enova Advanced®					
Material	Single Piece, 100% Glistening-Free, Hydrophobic Acrylic, Dry-Packed				
Refractive Index	1.53 (546 nm)				
Glass Transition Temperature (Tg)	-2°C				
Water Content	7%				
Square Edge	360° square edge				
Optic Diameter	6.00 mm				
Overall Diameter	13.00 mm				
Haptic Design	C-Loop				
Haptic Angle	0°				
Lens Color	Clear				
Photo Protection	UV Filtration				
Recommended Constants	Ac A constant: 118.0 SRK-II: 118.7 SRK-T: 118.7 Haigis a0, a1, a2: 1.11, 0.4, 0.1 HofferQ pACD: 5.37 Holladay sf: 1.62 Barrett Universall LF: 1.73				
Optic Design	Non-diffractive EDOF IOL with Light Tailoring Technology, Biconvex Aspheric, Aberration Neutral				
Spherical Power Range	+10.00 D to +30.00 D (with 0.50 increments)				
Recommended Injector System	Rotaryjet Preloaded System (2.2mm - 2.4mm)				
Enova Advanced® Toric					
Cylindrical Power Range	PAD2*	PAD3	PAD4	PAD5	PAD6
	+1.00 D*	+1.50 D	+2.25 D	+3.00 D	+3.75 D
Optical Power Addition	2.2 (approx.)				

*Available soon

enova
Advanced[®]
Preloaded Extended Depth of Focus (EDOF) IOL

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