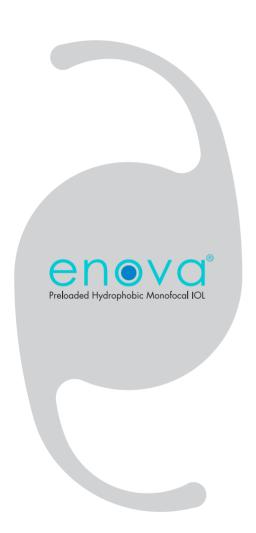
# Enovation of Hydrophobic IOLs







## Enovation of Hydrophobic IOLs



100% Glistening-Free Material



Outstanding Biomechanical Properties



Pre-Conditioning Free



Clinically Proven Low PCO Rate



Preloaded





### Enovation of Hydrophobic IOLs

Hydrophobic IOLs have evolved significantly over time, and Enova® represents the pinnacle of this evolution. That's why we call it "Enovation".



### 

Enova® is the only 100% glistening-free¹ hydrophobic acrylic IOL that requires neither pre-hydration nor storage in saline. Enova®, which has 7% water content, is dry-packed and has excellent optical and mechanical properties with a preloaded system.



#### 2<sup>ND</sup> Generation Hydrophopic IOLs

Hybrid polymers, which include less than 5% water content, demonstrate a so-called control over water uptake and improved resistance to glistening formation, albeit at reduced levels. However, IOLs made from such materials either have poor mechanical properties or require both pre-hydration and storage in saline<sup>2</sup>.



### **1ST** Generation Hydrophopic IOLs

Acrylic IOLs, with less than 1% water content<sup>3</sup>, develop various levels of glistening post-implantation due to uncontrolled water intake into the IOL polymers.

<sup>1-</sup> Glistening Analysis in Enova ® Hydrophobic Acrylic Intraocular Lenses / In-vitro Study Evaluating the Tendency of Different Intraocular Lenses to Form Intraoptical Glistenings by the University of Utah

<sup>2-</sup> Bausch & Lomb. enVista Directions for Use

<sup>3-</sup> Comparative analysis of in vitro accelerated glistening formation in foldable hydrophobic intraocular lenses. International Ophthalmology Tandogan, T., Auffarth, G. U., Choi, C. Y., Son, H.-S., & Khoramnia, R. (2021).





### Enovation of 100% Glistening-Free IOL Material

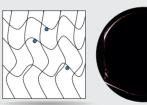
The Enova® IOL Material is the first 100% Glistening-Free hydrophobic acrylic IOL that does not require pre-hydration and storage in saline solution!

The Enova® PGF3 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."





One year after the implementation

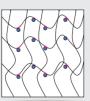




#### **ENOVA® 100% Glistening-Free IOL**

The unique composition of Enova® 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









### Enovation of 100% Glistening-Free IOL Material

#### **Conclusion by the University of Utah**

Study: In vitro study evaluating the tendency of different intraocular lenses

to form intraoptical glistenings:

STUDY REPORT

Intermountain Ocular Research Center John A. Moran 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. Tecnic 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

Liliana Werner MD PhD

Nick Mamalis, MD



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.

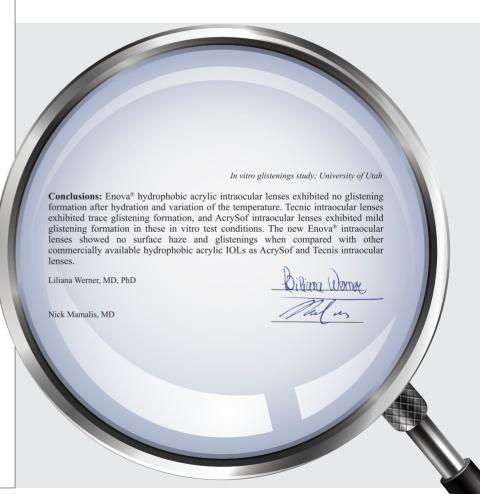
- Enova® IOLs: No glistening, no haze.
  Acrysof IQ IOLs: Mild optic haze (giving the lens a slight yellowish/brownish) discoloration under light microscopy) and mild glistening formation. Diameter of the glistenings: 10 to 20 microns.
- Tecnis (OLs: Moderate central optic haze (giving the central part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

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

Table 1 : Number of Microvacules Converted to MV/mm



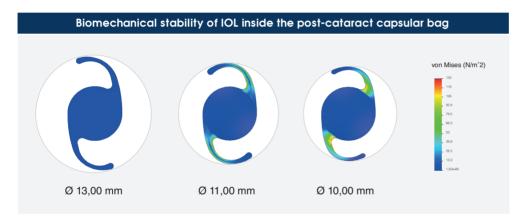




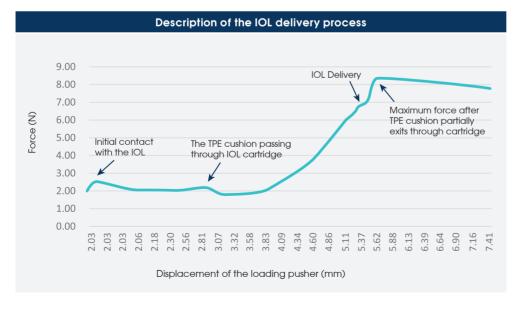


### Outstanding Biomechanical Properties

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.

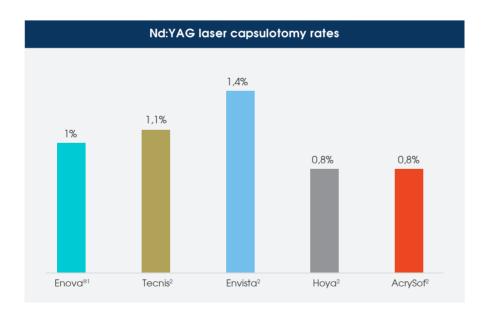




### Clinically Proven Low PCO Rate

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

In the multicenter studies performed on Enova® 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.



<sup>1-</sup> VSY Biotechnology Data on File, 2023.

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





### No Pre-Conditioning Required

A polymer's Glass Transition Temparature (Tg) is reached when the polymer changes from a rigid material to a soft material. Having a Tg of  $-2.0^{\circ}$ 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.

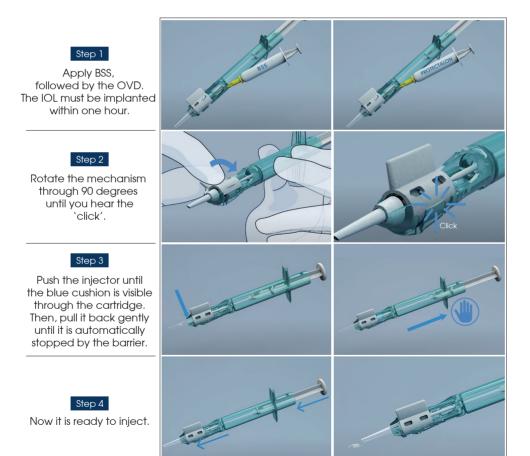
IOL	Tg (°C)	Glistening	Packaging State	
en <b>o</b> va°	-2.0	No	Dry	
AcrySof Vivity®	15	Yes	Dry	
Tecnis®	14	Yes	Dry	





### Ready-to-Go Preloaded System

Due to its patented Rotaryjet technology, the Enova® 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.







## Technical Features

Enova® PGF3				
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 Universalli LF: 1.73			
Optic Design	Monofocal, Biconvex Aspheric			
Spherical Power Range	Preloaded	From +6.00 D to +30.00 D (0.50 D increments)		
	Standalone*	From 0.00 D to +32.00 D (0.50 D increments)		
Recommended Injector System	Rotaryjet Preloaded System ( 2.2mm - 2.4mm )			

<sup>\*</sup>Recommended injector system: Acrijetfly



