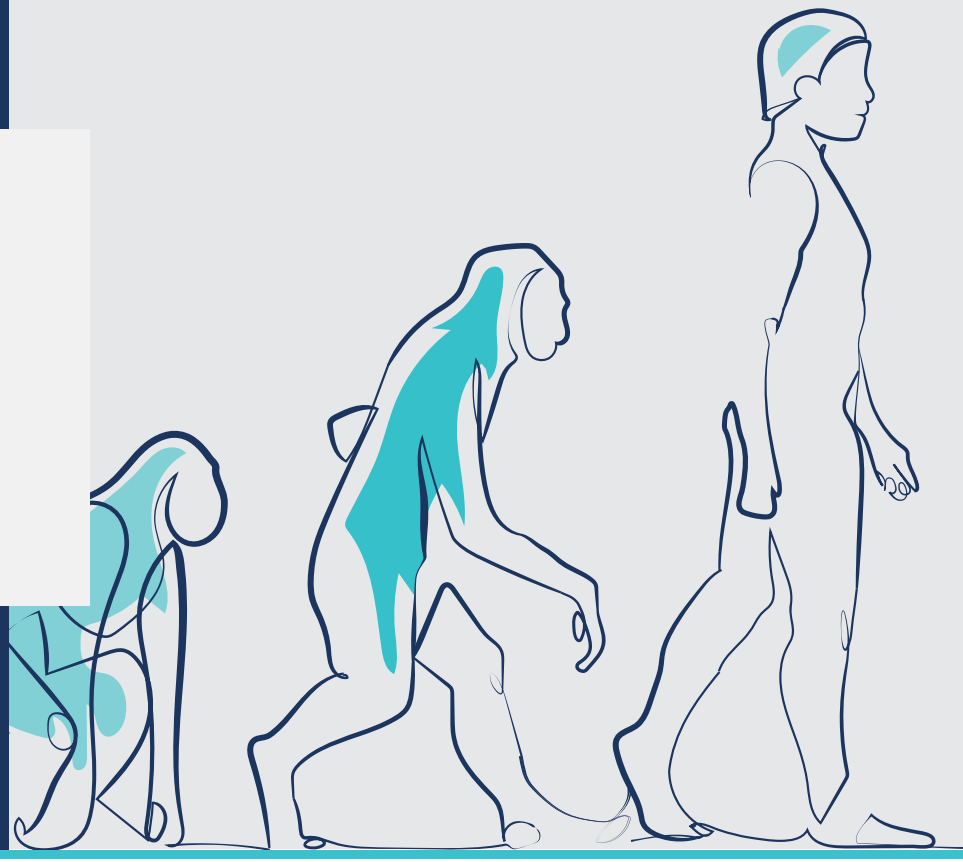
Enovation of Hydrophobic IOLs

enova®

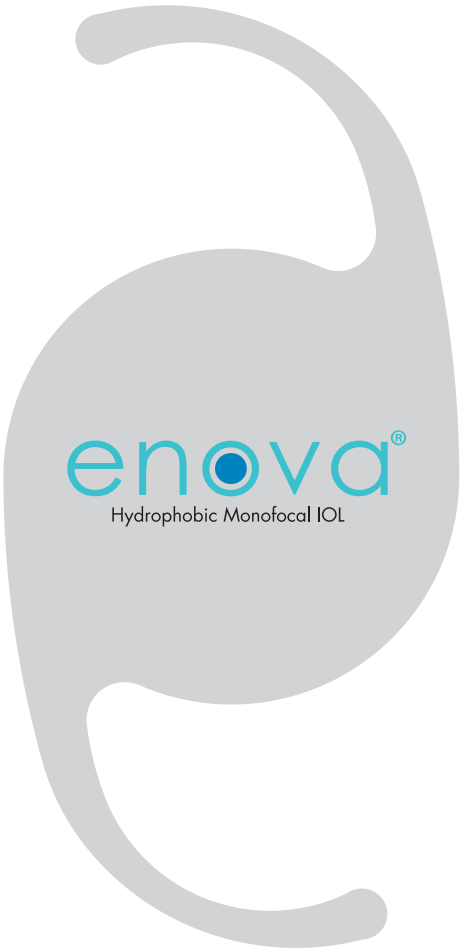
Hydrophobic Monofocal IOL



VSY BIOTECHNOLOGY

we inspire...

Enovation of Hydrophobic IOLs



100%
Glistening-Free Material

Outstanding
Biomechanical Properties

Clinically Proven
Low PCO Rate

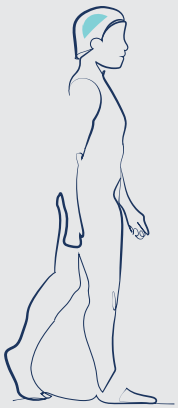
—Low—
PCO

Pre-Conditioning Free

Tg
-2℃

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® Generation

Enova® is the only 100% glistening-free[1] 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.

2ND 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[2].

1ST Generation Hydrophopic IOLs

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

1- 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
2- Bausch & Lomb. enVista Directions for Use
3- 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).

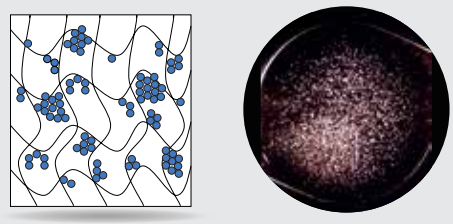
Enovation of 100% Glistening-Free IOL Material

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® GF3 IOL is dry-packed and boasts exceptional optical and mechanical properties.

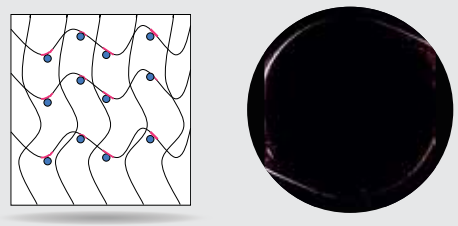
Glistening Formation in IOL

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."



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.



100%
unique hydrophobic IOL material
in-house production
EST. 2009

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 intraocular 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 lenses.

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.

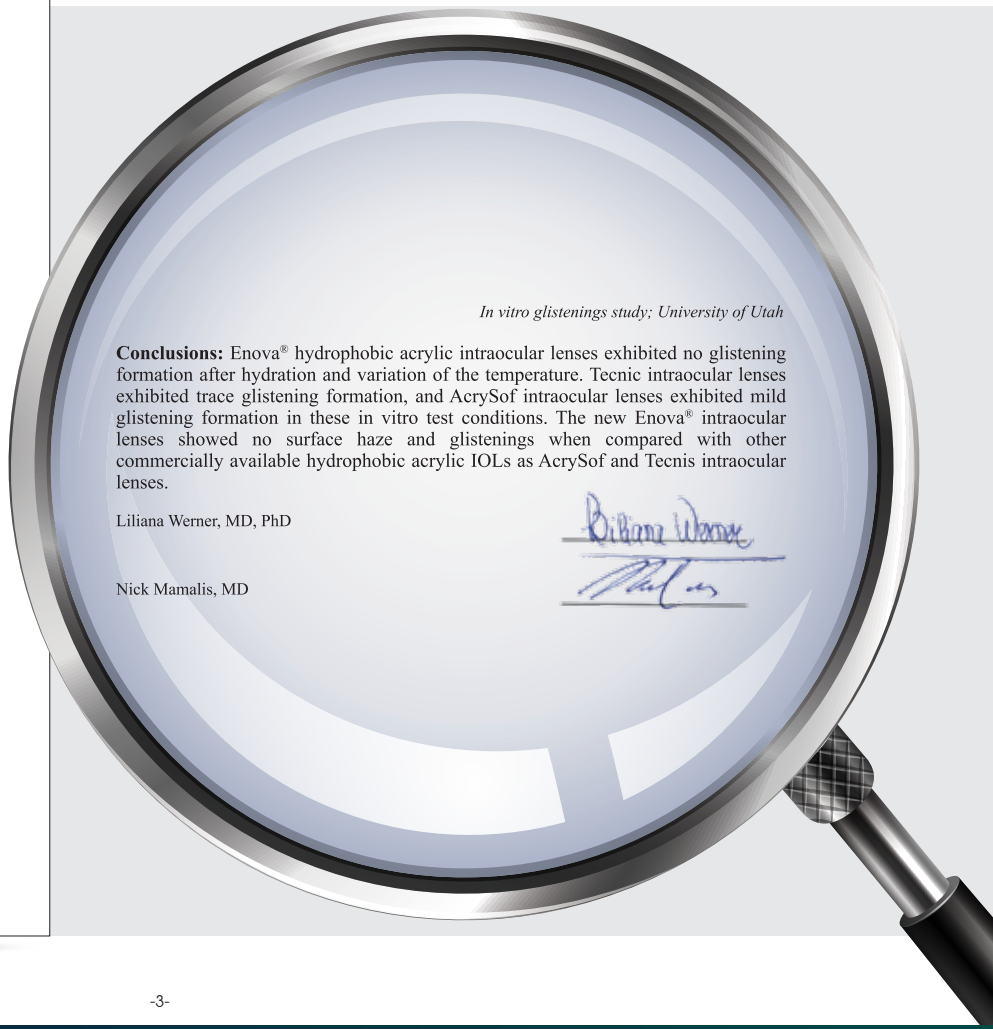
- Enova® IOLs: No glistening, no haze.
- Acrysof IQ IOLs: Mild optic haze (giving the lens a slight yellowish/brownish discoloration under light microscopy) and mild glistening formation. Diameter of the glistenings: 10 to 20 microns.
- Tecnis IOLs: Moderate central optic haze (giving the central part 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 mm^2) were counted, and the results were converted to MV/mm^2.

IOL	MV/mm^2 Week 1
Enova®	0
AcrySof IQ	8.7
Tecnis	2.9

Table 1 : Number of Microvacules Converted to MV/mm^2

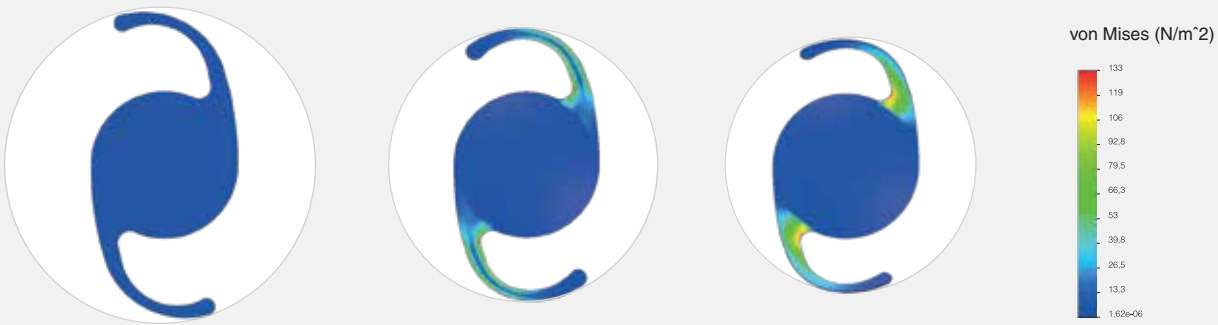
THE UNIVERSITY OF UTAH



Outstanding Biomechanical Properties

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

Biomechanical stability of IOL inside the post-cataract capsular bag



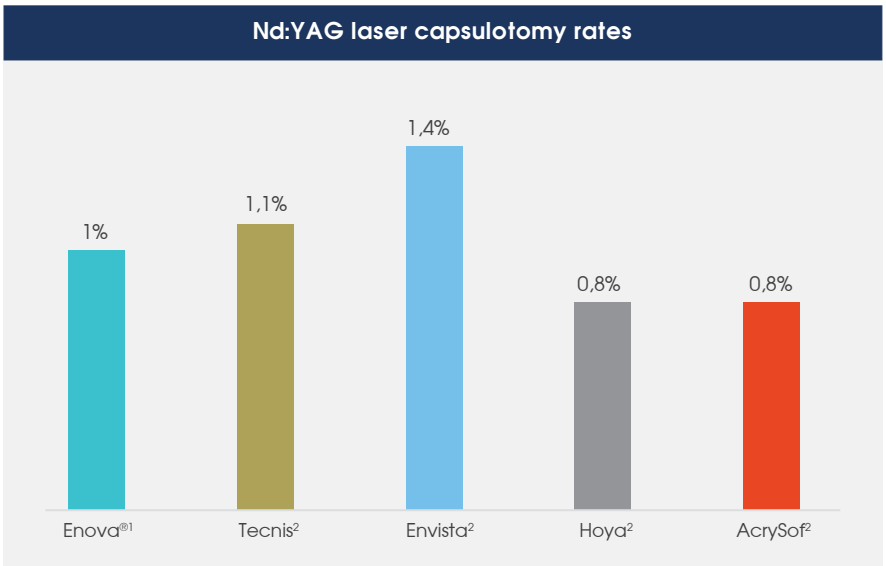
Ø 13,00 mm Ø 11,00 mm Ø 10,00 mm

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

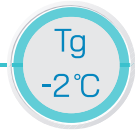
Clinically Proven Low PCO Rate

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.



1- VSY Biotechnology Data on File, 2023.
2- 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°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
enova®	–2.0	No	Dry
AcrySof Vivity®	15	Yes	Dry
Tecnis®	14	Yes	Dry

Technical Features

Enova® GF3		
Material	Single Piece, 100% Glistening-Free, Hydrophobic Acrylic, Dry-Packed	
Optic Design	Monofocal, Biconvex Aspheric	
Refractive Index	1.53 (546 nm)	
Glass Transition Temperature (Tg)	-2°C	
Water Content	7%	
Optic Diameter	6.00 mm	
Overall Diameter	13.00 mm	
Haptic Design	C-Loop	
Haptic Angle	0°	
Spherical Power Range	Standalone	From 0.00 D to +32.00 D (0.50 D increments)
Lens Color	Clear	
Photo Protection	UV Filtration	
Recommended Constants	Ac A constant: 118.0 SRK-II : 119.03 SRK-T: 118.7 Haigis a0, a1, a2: 1.11, 0.4, 0.1 HofferQ pACD: 5.33 Holladay sf:1.55 Barrett Universalll LF:1.73	
Recommended Injector System	Acrijetfly 2.2	

enova®

Hydrophobic Monofocal IOL

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VSY BIOTECHNOLOGY

we inspire...

VSY Biotechnology GmbH
Esslinger Str.7 70771 Leinfelden-Echterdingen Germany
contact@vsybiotechnology.com / www.vsybiotechnology.com

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