



EZ Toric

Preloaded
PreciSAL

MIBI
MILLENNIUM
Biomedical Inc.



MBI

Experience the beauty with new vision

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Make a difference every time

We believe perfect eyesight can be restored. It's not a theory, it's a reality.

PreciSAL is an aspheric intraocular lens with negative spherical aberration. It will transform patients' lives by giving them back what they thought was lost forever - a clear, sharp vision.

PreciSAL is a revolutionary new technology, proprietary to MBI.

As people who care about eyesight, we want to see optimum results, and to see them consistently. We want the products we offer to be reliable and of the highest quality. We want to be certain we are helping you make a difference every time you treat someone.

While some are content to use current technology, MBI embraces the forward thinkers of this world - the people who are developing tomorrow's technology.

PreciSAL

MBI More than meets the eye | 1 |



Our goal is to supply surgeons with the world's best hydrophobic acrylic IOLs.

Why you should choose MBI

We delve for difference, we search for innovation, and we insist on world's best technology and precision manufacturing.

We are committed to manufacture truly innovative products. But that's still not enough – Our vision is truly focused on making a difference in people's lives.

You will be inspired by MBI because you look for the highest quality and innovation in medical device.

Our goals are built on supplying surgeons with the world's best hydrophobic IOLs - PreciSAL (Precision Soft Acrylic Lenses).

We deliver IOLs with a 0.25 Diopter precision (currently only available in Australia).

We believe our unique Material has no micro-vacuoles and no mie-scattering. MBI's PreciSAL IOLs provide patients with outstanding contrast sensitivity and visual acuity.

Our Products are easy to use.

MBI is a FDA registered and ISO 13485 certified company. We are located in Southern California. MBI has been engaged in the development, prototyping and manufacturing of innovative medical products since 1997.

All work are carried out at MBI. By combining the Medical preloaded Injector with MBI IOL together, we offer an excellent injectable lens system to our customers.

We not only meet the ISO standards, we strive to exceed them.



PreciSAL

Our vision is clear

The proprietary material, unique manufacturing processes and 0.25D lens power precision make PreciSAL a vastly superior product. PreciSAL out-performs all other IOLs in every way including quality, precision, performance, usability and repeatability, and represents a significant advancement in ophthalmic surgery. By using the preloaded injector from Meditel AG, MBI offers an excellent and optimized lens delivery system.

Manufactured in 0.5 Diopter increments* to a tolerance of only $\pm 0.25D$ in a range from 10D – 30D, you can be assured that what's labeled on the box is what's in the box.

* Diopter range details on pages 18,19, 20.



Preloaded PreciSAL

PreciSAL quality

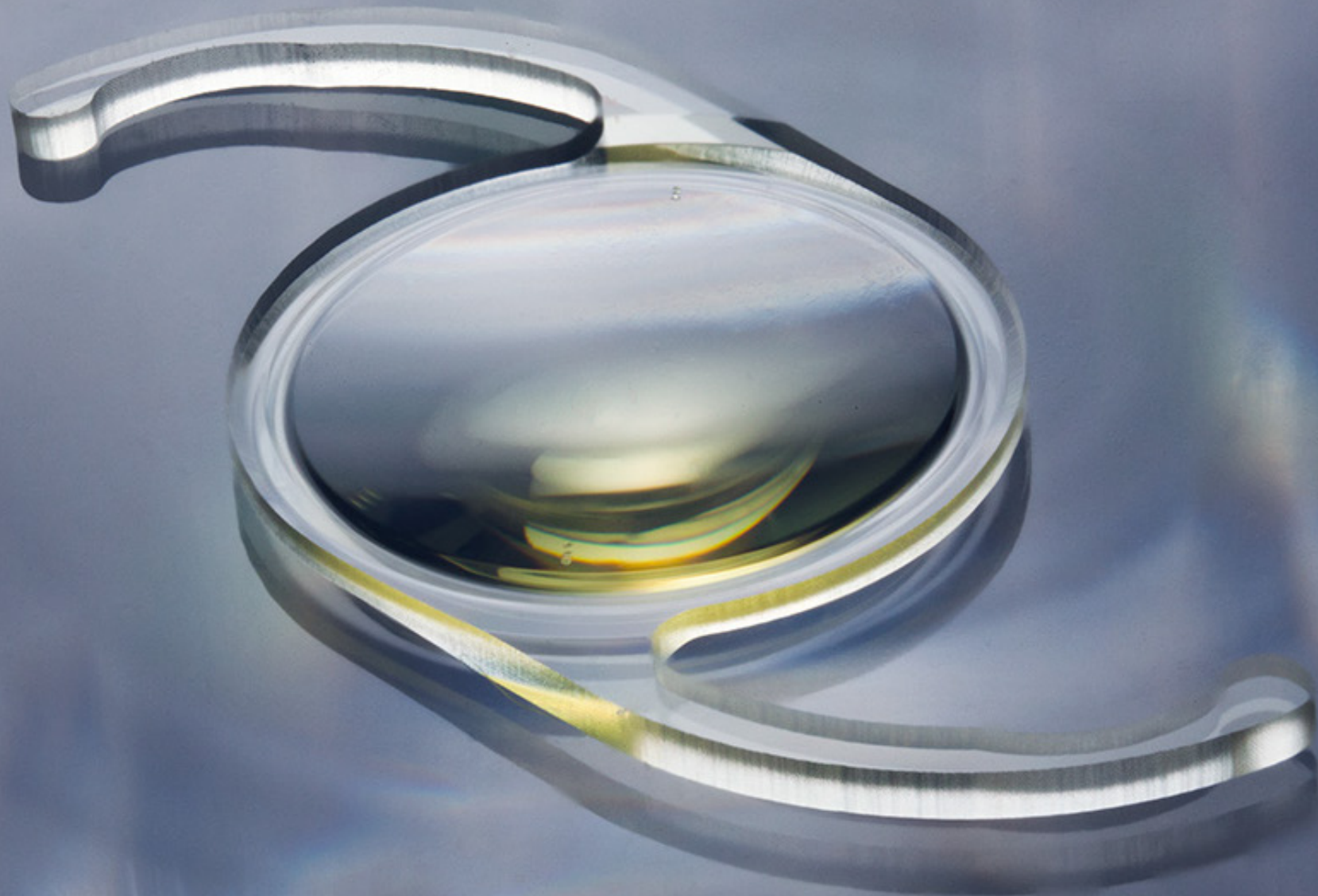
PreciSAL Clear IOLs are made from a unique soft hydrophobic acrylic material, with less than 0.5% water content that incorporates the most desirable UV blocking properties. PreciSAL Yellow IOLs have the same benefits, with the addition of a proprietary blue-light filter.

The lenses unfold and center perfectly, and position in the capsular bag exactly where you want them, making them easy to implant. In fact, there is no need to change your implant technique – PreciSAL lenses are intended to be inserted through a 2.4mm or less incision with MBI's Preloaded injectable lens system, or with the injection system recommended on our product specification sheets.

They are simply beautiful to use.



PreciSAL
A High Definition IOL



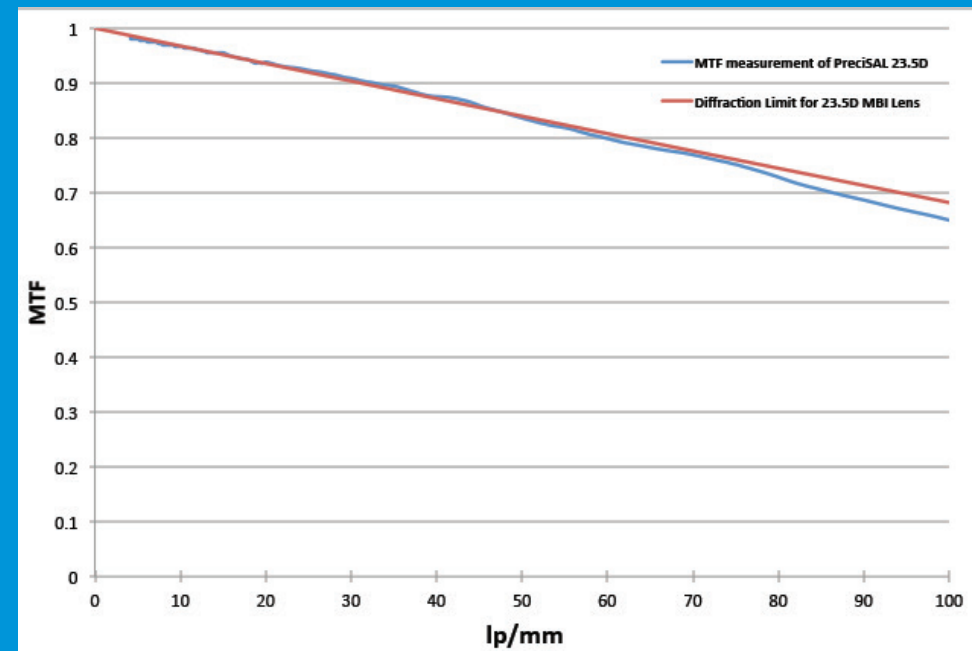
MTF of PreciSAL

Modulation Transfer Function (MTF) is the most superior tool for objectively measuring image quality, visual acuity and contrast sensitivity.

PreciSAL has an excellent MTF value (as high as 0.65 at 100 lp/mm), because of the high precision in manufacturing and the unique acrylic material of MBI.

PreciSAL simultaneously offers both the advantages of enhanced visual acuity and good depth of focus.

PreciSAL is a unique product
for your patient.



PreciSAL



Optical precision

PreciSAL means using the best, not the adequate.

We believe the current tolerance limit for diopter powers in IOL power labeling (established by the International Standards Organization) could be improved to significantly reduce today's refractive errors.

Take a 20 Diopter IOL, for example: 20D is written on the box, but the ISO tolerance allows for an error of $\pm 0.4D$. The IOLs could actually be anywhere from 19.6D – 20.4D. Added to this are the constraints of 0.5D steps, and the judgement involved in selecting the appropriate power. This creates the potential for a refractive error of up to $\pm 0.7D$. The error can be even more significant with higher powered lenses. This means a patient could be given, quite unintentionally, IOLs that are almost one diopter off target.

We believe it's better to have the lens fit the patient, rather than the other way around.

We believe that what's labeled on the box should be what's in the box.

PreciSAL

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Chromatic aberration

PreciSAL lenses have a high Abbe number.

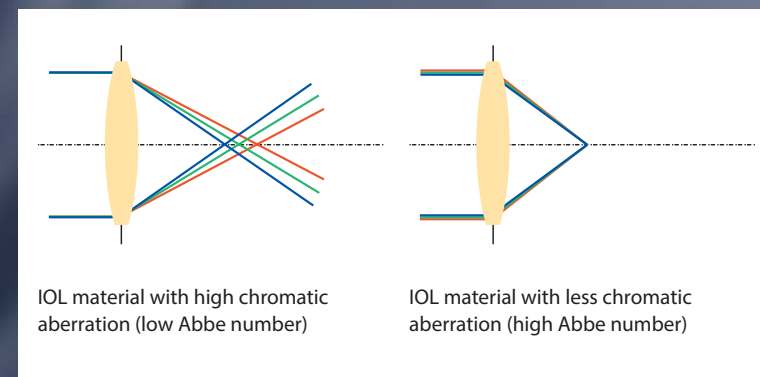
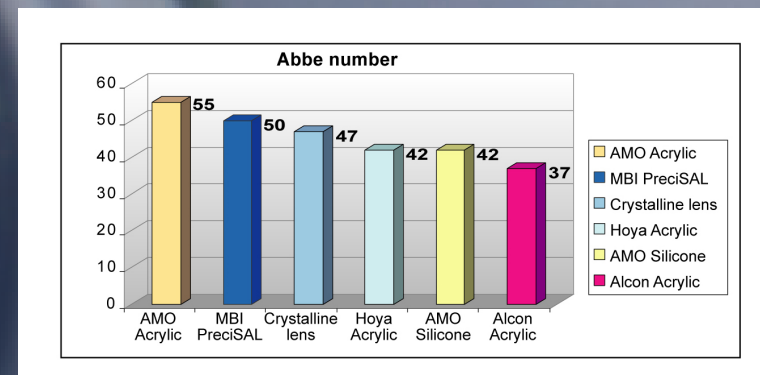
That's a good thing.

The Abbe number, also known as the V number, is a measure of a transparent material's dispersion in relation to the refractive index, with high values of V indicating low dispersion (or low chromatic aberration).

In optics, the Abbe number indicates material quality and the capability of an IOL to focus all colors to the same point. A high Abbe number not only means less chromatic aberration, but also better contrast and optical performance.

We are proud of our V number. PreciSAL lenses have an Abbe number of 50*.

*Abbe number: Source of Abbe numbers except PreciSAL : Zhao H. Mainster M. J. Cataract Refract Surg. 2007, Zhao H, et al. Presented at ESCRS 2009.



PreciSAL design

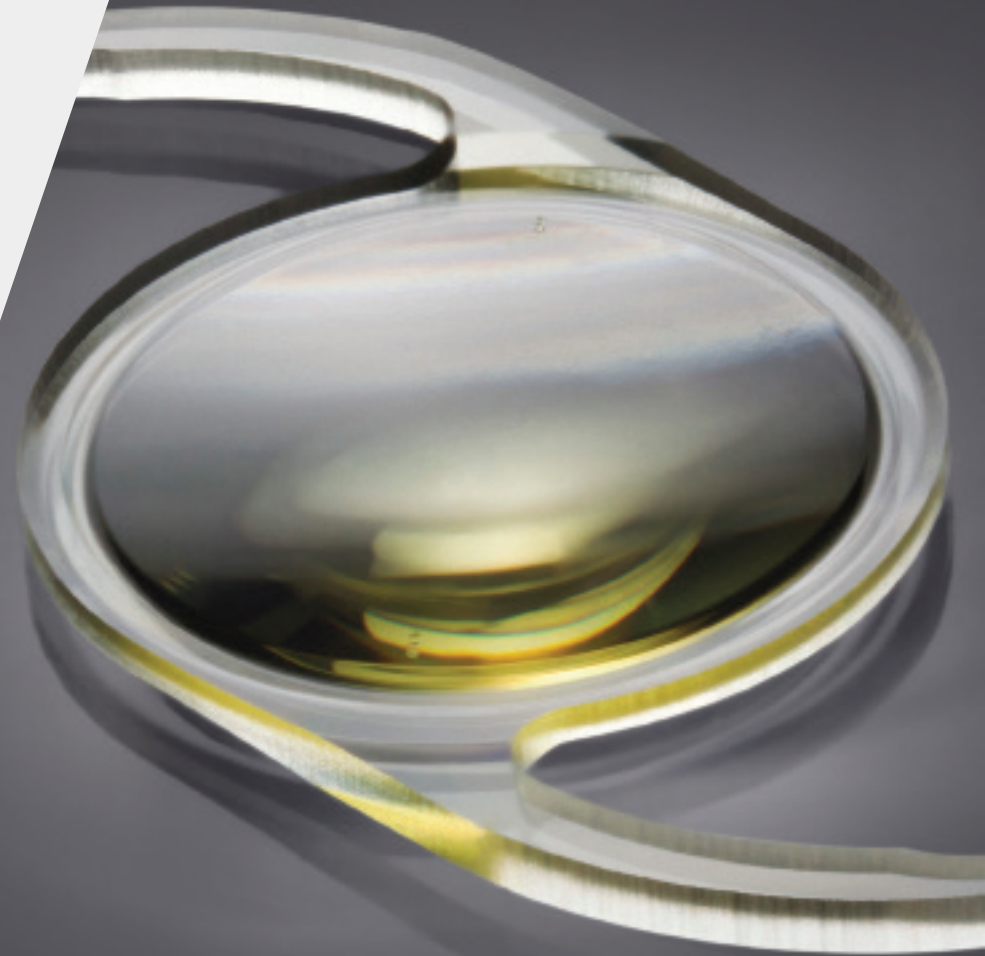
The way an IOL performs is defined by how it is made.

The general way – Injection Moulding is used to make hydrophobic acrylic IOLs. This process can create micro cracks and spaces between the lens material polymer chains. Over time, water in the material, along with aqueous, may condense into these spaces, forming fluid-filled micro vacuoles. These glistenings may then create mie-scattering within the eye, causing a significant loss of contrast and a decline in visual acuity.

The MBI way – The PreciSAL manufacturing process is state-of-the-art.

It's the MBI material and ultimate precision of our lathing technique, which makes PreciSAL exceptional.

Since the launch of PreciSAL in 2008, no glistenings have been reported.

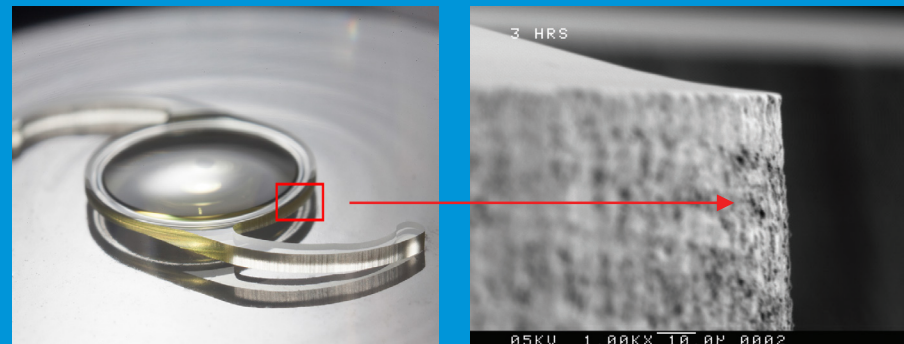
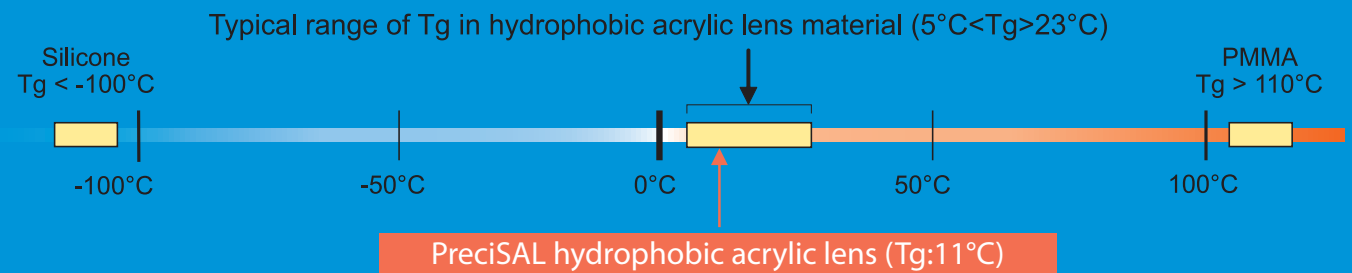


It's also about finesse.

The MBI innovative manufacturing process delivers a square edge all around the optic and the haptic edges. We believe that this square edge contributes to blocking cell migration and minimizing PCO.

Engineered with a low glass transition temperature (Tg), PreciSAL is also designed for the operating room: the material becomes soft and easy to inject. No waiting, no pressure – just simple smooth unfolding.

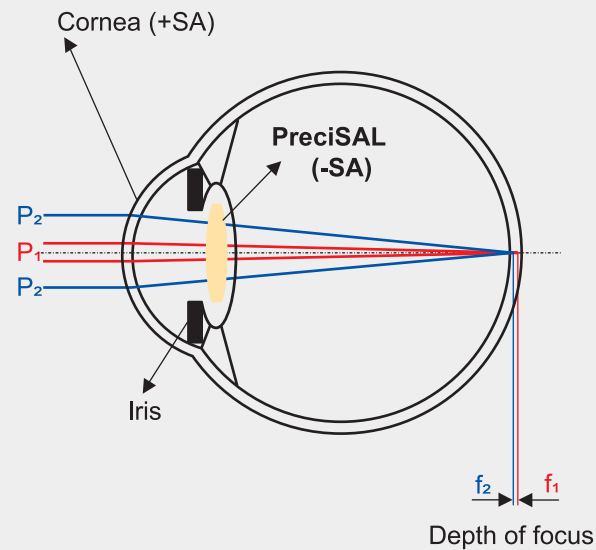
The unique PreciSAL proprietary material is soft and pliable for ease of folding and implantation.



SEM picture with 1,000 x magnification, showing the 90° edge of the PreciSAL optic under the scanning electron microscope.

PreciSAL

PreciSAL asphericity



Your patients want clear, crisp sight in all conditions – day, night, dim or bright.

We offer it with PreciSAL.

Contrast sensitivity is particularly important in environments such as driving at night or dining in a dimly lit restaurant.

Negative spherical aberration (-SA) improves vision in these situations, producing the best visual acuity and contrast sensitivity with a modest depth of focus.

PreciSAL



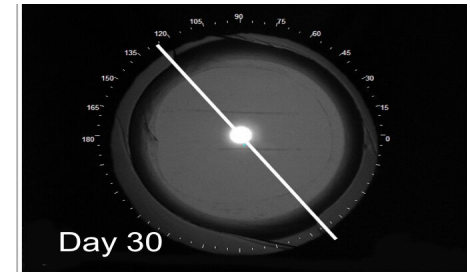
PreciSAL results

PreciSAL is available in 0.5 Diopter increments from 10.0D to 30.0D with a manufacturing tolerance of $\pm 0.25D$, so you can give your patients exactly what their vision needs.

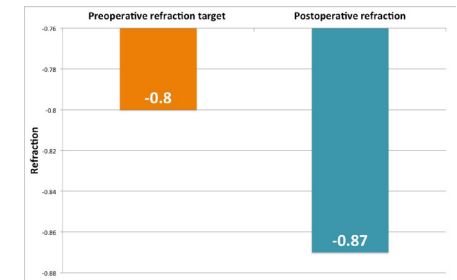
In a recent Australian study* the sight of 100 consecutive PreciSAL recipients was tested 3 months after surgery, where 89% of these patients were within 0.5D of target refraction.

The result is unprecedented.
The patients overjoyed.

* Conducted by Dr. Peter Stewart, Lasersight Marochydore (2013). Data available on file, MBI Lenses of $\pm 0.125D$ tolerance were used.



Drs. Dosso and Dreifuss, from Geneva Switzerland, have observed clinically that the mean rotation of their patients' PreciSAL Toric IOLs is only 1.2 degrees after 30 days.



Dr. Dosso's mean pre-operative target refraction was $-0.80D$ across his patient profile and the mean post-operative refraction result was $-0.87D$, where 86% of all eyes implanted with PreciSAL Toric IOLs were within 0.5D of target refraction.

EZ Toric^{1,2} - The Cutting Edge difference

Easy to use, with precise, reliable results.

That's what PreciSAL EZ Toric lenses bring to you as a surgeon. What we try to do for patients is to correct their astigmatism, and bring them back to a world of color, contrast and clarity.

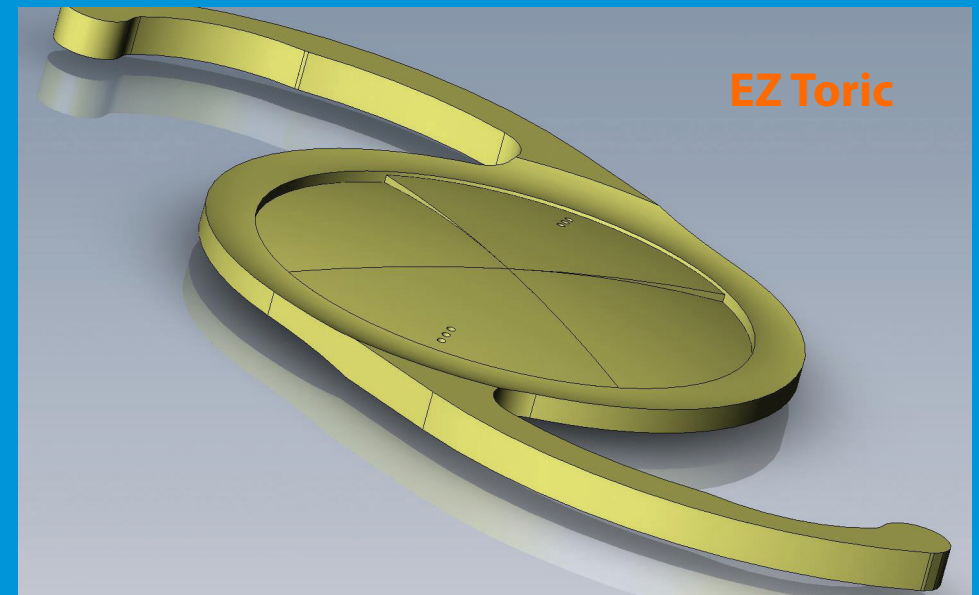
The lathe-cut technology used to create PreciSAL lenses provides precision and clarity that we believe is unmatched in the world of ophthalmology. It's precision you can see.

Less rotation – We believe that the lens is easy to position and remains relatively stable once positioned in the capsular bag because of our lens design and manufacturing process. We believe that the MBI process provides a good coefficient of friction on the finished edges which, in turn, facilitate a much better attachment of the capsular bag to the lens post-op to hold it in place.

The precise quadrant lathing is intended to spread the lens power over a greater area and, therefore, far more forgiving in rotational misplacement. In conjunction with the intended improved attachment of the lens to the capsular bag, PreciSAL EZ Toric promotes lens positioning that is intended to be fail-safe.

Greater accuracy / more capacity – Both spheres and cylinders are available in 0.5 Diopter increments, providing our vision of great accuracy in treatment. Cylinders start at 1.0D, so you'll be able to treat the majority of people more effectively.

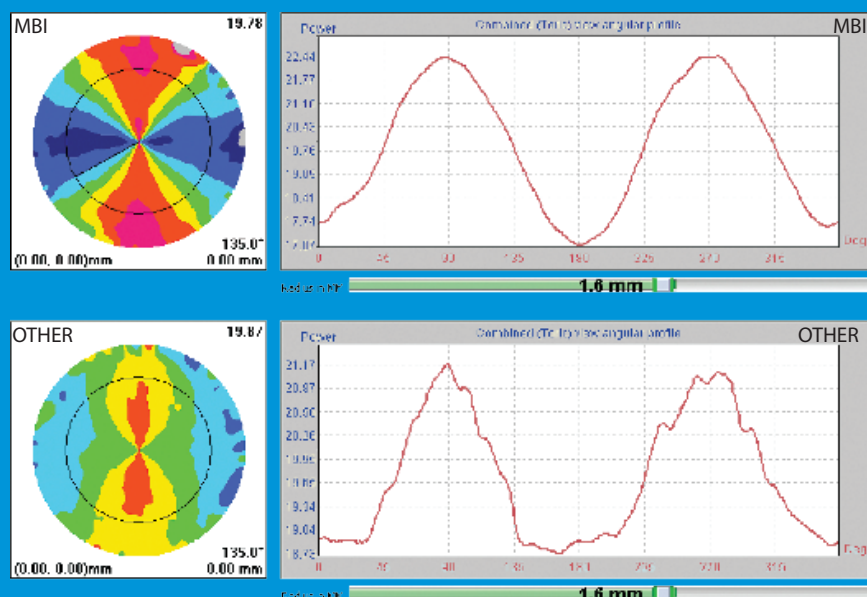
The way we've manufactured, the ease with which we perform, and the results we achieve, will take you and your patients to a new level of satisfaction.



The figure above shows the quadrants of a PreciSAL EZ Toric IOL. The two steeper quadrants have increased curvature (added power) for the cylinder, and blend crisply with the flatter (reduced power; marked with three dots) quadrants. The cylinder quadrants have a straight and minimal transition zone to the sphere, meaning the cylinder correction covers up to 85° of the available 90° surface. The quadrants also extend to within 0.5mm of the optic edge, so the power is more precise across a significantly greater area from competing Toric IOLs. PreciSAL EZ Toric is more forgiving of both rotation and off-axis implantation, as well as providing a crisp, clear astigmatic correction.

1: continued european clinical study
2:Trade Mark Pending

EZ Toric

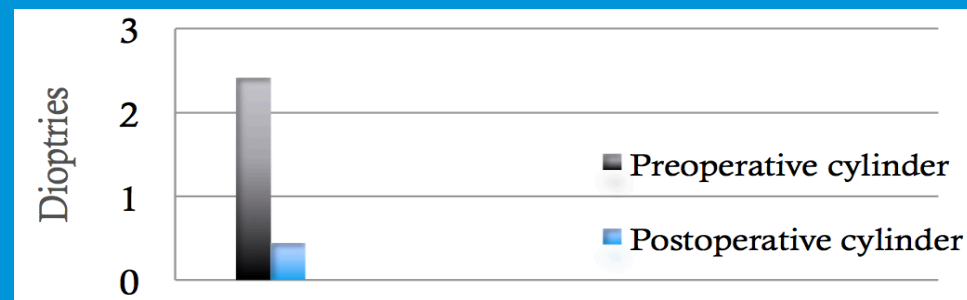


The superior manufacturing capability of the MBI EZ Toric lens is compared to “other” manufacturer in the above topography and histogram. The transition edge between cylinder and sphere is much better defined by the MBI PreciSAL EZ toric IOL.

The mean preoperative keratometric cylinder was 2.41D (range 1.5 to 3.25D) and the postoperative refractive cylinder was 0.44D (range 0 to 0.75D)

At day one, the mean axis misplacement was 6.3° (range 0 to 12°). At one month, the mean IOL rotation was 1.2° (range 0 to 3°). None of the IOLs required realignment.

...the good tolerance of some axis misplacement of MBI EZ Toric IOL allows achievement of excellent postoperative visual outcomes.



Note: Presented at 2017 ESCRS Meeting in Lisbonne by Andre Dosso, M.D., Geneva, Switzerland.

PreciSAL

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PreciSAL Yellow

PreciSAL Yellow is not the yellow lens you think it is.

It looks different because it is different.

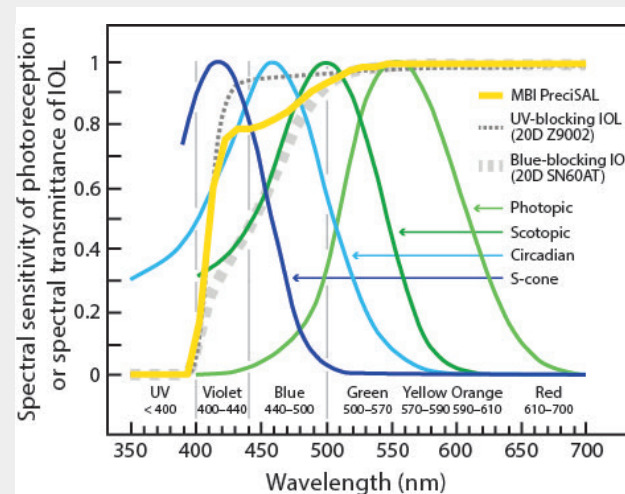
PreciSAL Yellow gives your patients the clarity and filtering properties similar to the lens of a 4½ year old. They will have clearer and crisper vision.

The high-energy filter protects the macula from cytotoxic violet light. However, it doesn't block all the benign blue-light wavelengths (440nm–500nm) that contribute significantly to the body's sense of diurnal rhythm, effective dim-light vision, colour perception and circadian photoreception.¹

With PreciSAL Yellow, MBI achieves this with transmission values of 78%–94% (440nm–500nm) compared to the industry standard of 32%–81%. Therefore, PreciSAL Yellow more accurately replicates the spectral transmission of a normal, healthy eye.

We believe your patients will see better and sleep better – their lives will be transformed.

Spectral sensitivity of photoreception and spectral transmittance of IOLs²



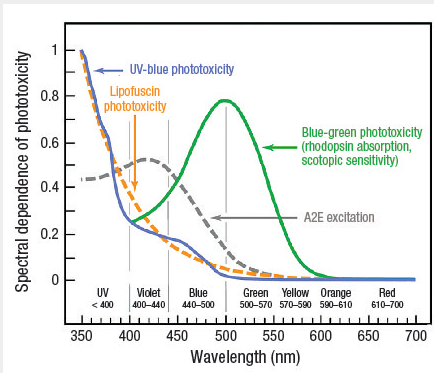
S-cone (Imax z 420 nm), circadian (Imax z 460 nm), aphakic scotopic (Imax z 500 nm) and photopic (Imax z 555 nm) spectral sensitivities, where Imax is the wavelength of peak spectral sensitivity... The spectral transmittances of [PreciSAL 302A (20D)], a UV-blocking (AMO Tecnis Z9002 20D), and a blue-blocking (Alcon AcrySof Natural SN60AT 20D) IOL are also shown.

1 Except the MBI spectral transition curve, source of graphic: Mainster M.A., Turner P.L.: 'Blue-blocking IOLs Decrease Photoreception Without Providing Significant Photoprotection', Table 1. Surv. Ophthal. 55(3) May- June 2010 p 273. 2010

2,3,4 Reprinted from Survey of Ophthalmology, Vol 55, Number 3, May-June 2010, Mainster M.A., Turner P.L.: 'Blue-blocking IOLs Decrease Photoreception Without Providing Significant Photoprotection', pp 274–275. Copyright 2010, with permission from Elsevier.

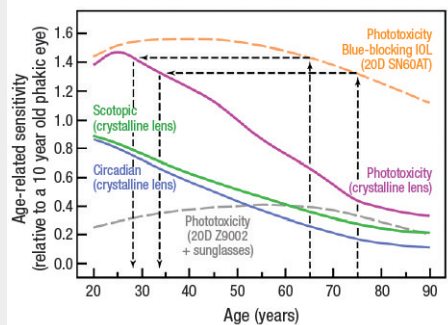
Believing is seeing

Spectral dependence of phototoxicity³



The action spectra for UV-blue phototoxicity and RPE lipofuscin phototoxicity are quite similar. Both increase rapidly with decreasing wavelength. Thus, UV-radiation is much more hazardous than violet light, which in turn is more hazardous than blue light. Acute blue-green retinal phototoxicity has an action spectrum similar to scotopic sensitivity...[where it]...peaks around 500 nm (blue-green) and decreases at shorter and longer wavelengths, as depicted in this figure by the absorption spectrum of rhodopsin.

Age-related sensitivity (relative to a 10 year old phakic eye)⁴



Acute retinal phototoxicity risk (UV-blue phototoxicity), scotopic sensitivity (rod photoreception) and circadian photoreception (melatonin suppression) for phakic eyes ("crystalline lens") relative to a 10-year-old phakic eye, taking into consideration age-related decreases in crystalline lens transmittance and pupil area and increases in RPE cell phototoxicity consistent with the age-related accumulation of lipofuscin.

We believe perfect eyesight is achievable.

We believe that 0.5D precision, $\pm 0.25D$ tolerance, no glistenings will transform people's vision.

We believe you can experience an unprecedented refractive accuracy, with up to 89% of patients being within 0.5D of target, because it's been shown across a study* of 100 consecutive patients in Australia.

We believe in embracing better ways, where attention to detail is unique. In hundreds of thousands implants, no glistenings were reported.

We believe **PreciSAL** will change the way you think about cataracts and give you the confidence to perform life-changing surgery, to believe in seeing, and restore what was thought lost.

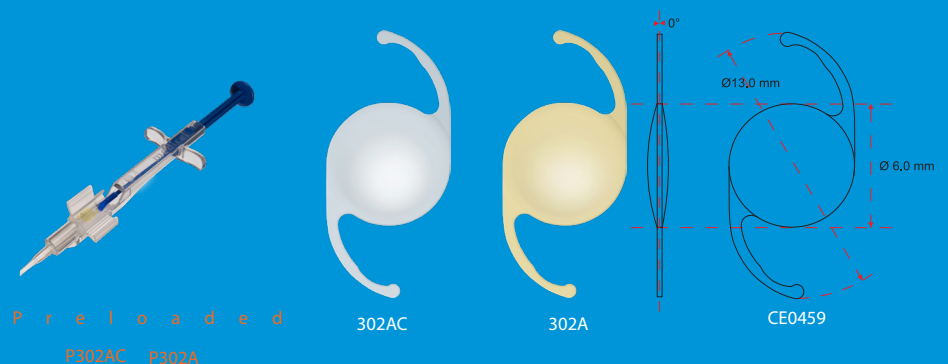
PreciSAL 1-Piece IOL Yellow and Clear

IOL design	Aspheric single piece posterior chamber lens
Material	UV Absorbing or UV+Blue-Light Filtering Hydrophobic Acrylic Polymer
Model	Preloaded: P302AC(uv) and P302A(uv+ blue-light filter) Non preloaded: 302AC(uv) and 302A(uv+blue-light filter)
UV cut off at 10% T (20D)	386nm ± 2nm (302AC), 388nm ±2nm (302A)
Material water content	<0.5%
Refractive index	1.5
Abbe number	50
Optic design	Biconvex, square edged optic and haptic
Haptic design	Modified C-Loop
Optic diameter	6.0mm
Overall diameter	13.0mm
Haptic angle	0°
Diopter range	Available in powers from 0.0D to 30.0D: 0.0D-10.0D in 1.0D steps 10.0D-30.0D in 0.5D steps
Manufacturer's A-constant	118.7 (for contact and immersion biometry)

Recommended A-constant*	•SRK II: 119.2 •SRK-T: 118.9 •sf: 1.75 [Holladay I] •HAIGIS: [a0: 1.32, a1: 0.40, a2: 0.10]
ACD ¹	5.337 [Holladay II]; 5.51 [Hoffer Q]; 5.51 [Manufacturer]
Method of sterilization	Ethylene Oxide (ETO)
Recommended Insertion Instrument	A suitable Preloaded Injector (Medcel) Non Preloaded: Medcel AG: Accuject LP604535 or ASB2200, 2.2 - 2.4mm Incision MDJ: Mini Glider, 2.2mm Incision, cartridge Mini B

¹: These values are shown as guidelines only for use with optical biometry for calculation of implant power. MBI recommend that surgeons develop their own values based on individual technique, measuring equipment and desired post-operative results. In no way are these values meant to be definitive.

NOTE: Devices are not approved for sale in the US.



PreciSAL

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PreciSAL EZ Toric 1-Piece IOL Yellow

IOL design	Toric aspheric single piece posterior chamber lens
Material	UV+Blue-Light Filtering Hydrophobic Acrylic Polymer
Model	Preloaded : PT302A Non Preloaded: T302A
UV cut off at 10% T	388nm ± 2nm
Material water content	<0.5%
Refractive index	1.5
Abbe number	50
Optic design	Toric, biconvex, square edged optic and haptic
Optic diameter	6.0mm
Overall diameter	13.0mm
Haptic angle	0°
Spherical equivalent range	Available in spherical equivalent powers from 10.0D to 30.0D 0.5D steps
Cylinder range	1.0D to 6.0D in 0.5D steps
Manufacturer's A-constant	118.7 (for contact and immersion biometry)

Recommended A-constant*	•SRK II: 119.2 •SRK-T: 118.9 •sf: 1.75 [Holladay I] •HAIGIS: [a0: 1.32, a1: 0.40, a2: 0.10]
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MBI Toric Calculator: www.mbius.com/en/calculator.php

Barrett Toric Calculator: www.ascrs.org/barrett-toric-calculator

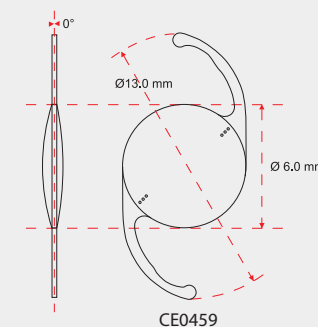
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P r e l o a d e d
PT302A



T302A



CE0459

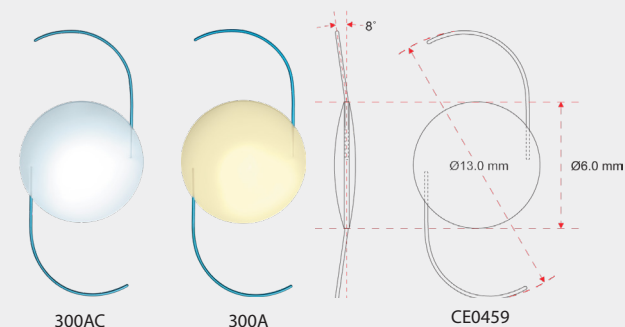
PreciSAL 3-Piece IOL Yellow and Clear

IOL design	Aspheric three piece posterior chamber lens
Material	UV Absorbing or UV+Blue-Light Filtering Hydrophobic Acrylic Polymer
Model	Models 300AC(uv) and 300A(uv+ blue-light filter)
UV cut off at 10% T	386nm ± 2nm (300AC), 388nm ± 2nm (300A)
Material water content	<0.5%
Refractive index	1.5
Abbe number	50
Optic design	Biconvex, square edged optic and haptic
Haptic design	C-Loop
Haptic material	PMMA
Optic diameter	6.0mm
Overall diameter	13.0mm
Haptic angle	8°
Diopter range	Available in powers from 0.0D to 30.0D: 0.0D-10.0D in 1.0D steps 10.0D-30.0D in 0.5D steps

Manufacturer's A-constant	118.3 (for contact and immersion biometry)
Recommended A-constant*	•SRK II: 118.9 •SRK-T: 118.7 •sf: 1.61 [Holladay I] •HAIGIS: [a0: 1.26, a1: 0.40, a2: 0.10]
ACD ¹	5.337 [Holladay II]; 5.51 [Hoffer Q]; 5.39 [Manufacturer]
Method of sterilization	Ethylene Oxide (ETO)
Recommended Insertion Instrument	Medicel Naviject Injector Model LP604405, Incision 2.8mm MDJ, Model MEPLAT with 00264 cartridge, Incision 2.8mm

¹:These values are shown as guidelines only for use with optical biometry for calculation of implant power. MBI recommend that surgeons develop their own values based on individual technique, measuring equipment and desired post-operative results. In no way are these values meant to be definitive.

NOTE: Devices are not approved for sale in the US.





Experience the beauty with new vision[®]

PreciSAL

MBI More than meets the eye | 21 |

MBI Product Catalog – Brochure P/N 001-000-021, LBL092 Rev. M

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