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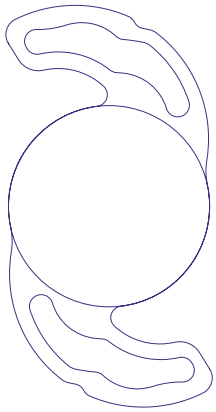

Precizon Go

Frequently asked questions (FAQ)

ophtec.com

How does Precizon Go achieve an extended range of vision from far to intermediate distance?

Precizon Go provides a wider range of clear vision from far to intermediate distances by extending the depth of focus of the patient. Such enlargement of the depth of focus is achieved by inducing a controlled amount of high-order spherical aberration.

In order to induce such spherical aberration Precizon Go has been designed with an **ingenious power profile** characterized by a **modified high-order aspheric anterior surface**. This means that the anterior surface of the lens has a **non-uniform power distribution** with a **gradual shift** from the center to the periphery (Fig. 1).

Looking more into depth into the profile of the Precizon Go IOL, there are **THREE** characteristics that explain the uniqueness and ingenuity of its engineering compared to other IOLs of its class (Fig. 1):

1. Central optics
The very **central part** of the optics of the lens (2 mm) is intended for **distance vision**. From there, the power profile starts increasing towards the periphery to extend the range of focus and provide intermediate vision. This constitutes a major difference with other Enhanced Intermediate Vision IOLs with aspheric designs, where the central part of the lens is intended for intermediate vision, and the power profile decreases towards the periphery to provide distance vision (Fig. 2).
Such innovative design is engineered to overcome one of the challenges of the Enhanced Intermediate Vision IOLs by **maintaining the best distance visio**n, while providing intermediate vision.

2. Power shift
At the mid-periphery of the lens, the power profile of the Precizon Go IOL suffers a shift. This shift initially increases the diopter power base and sequentially starts a new power decrease.
Such innovative design is intended to **boost intermediate vision** and also to **avoid a relevant magnitude of spherical aberration**. This constitutes a major difference with other Enhanced Intermediate Vision IOLs with aspheric designs, where the power profile continuously decreases from the center to the periphery with no shift on the direction (Fig. 2).
This way, Precizon Go overcomes additional challenges of the Enhanced Intermediate Vision IOLs by maintaining a **good quality of vision** at all distances and allowing a good **tolerance** and easy neuroadaptation process for the patient.

3. Power drop
At 1.5 mm from the center of the lens, there is a slight drop from the base diopter with another power shift upward. This is intended to compensate for the corneal and induced spherical aberration and, this way, to maintain a good far vision with no degradation. This feature also helps to maintain a good lens tolerance for the patient. This also constitutes a major difference with other Enhanced Intermediate Vision IOLs with aspheric designs, where the power profile continuously decreases from the center to the periphery with no shift on the direction, and therefore no compensation or the induced aberration (Fig. 2).

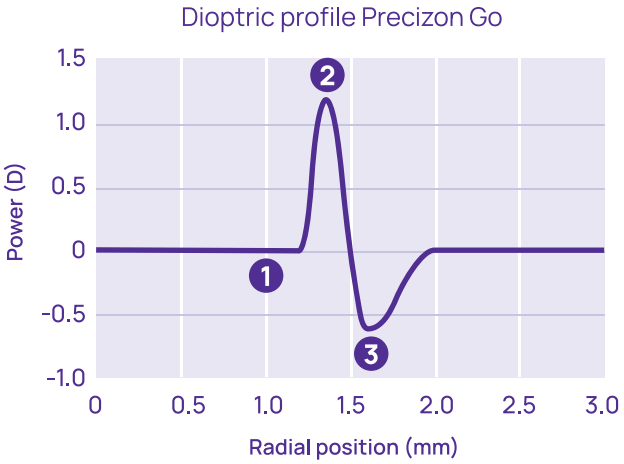

Figure 1. *Precizon Go has a **non-uniform power distribution** with a **gradual shift** from the center to the periphery. The figure shows the three main characteristics of the power profile of the Precizon Go IOL.*

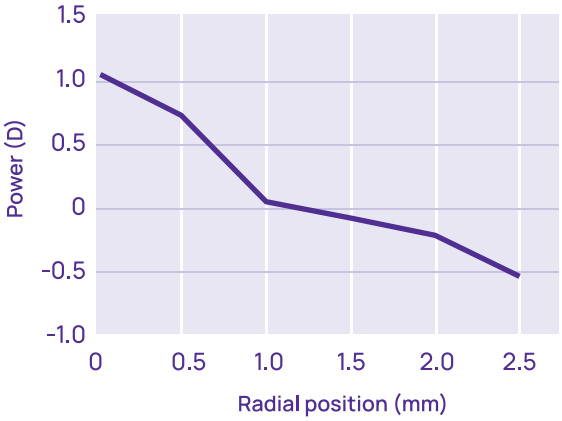

Figure 2. *Power profile of Enhanced Intermediate Vision IOLs with aspheric designs from competitors. As shown on the graph, the central part of the lens is intended for intermediate vision, and the power profile continuously decreases from the center to the periphery with no shift on its direction.*

How would the power profile of Precizon Go look like on a 3D Power Map compared to standard aspheric Enhanced Intermediate Vision IOLs?

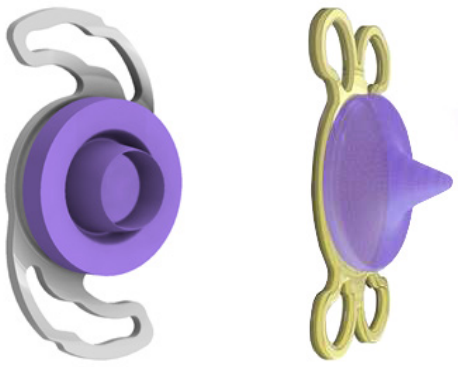

Figure 3. *3D Power profile of Precizon Go (left) and Isopure (right) IOLs. The three main characteristics that differ Precizon Go from other EIV IOLs can also be seen here on a 3D format.*

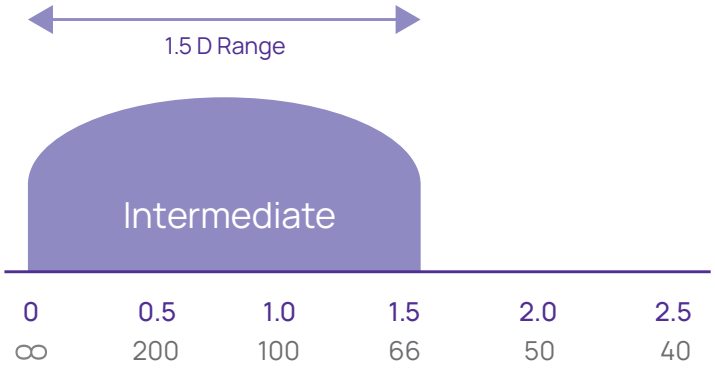

Figure 4. *According to internal bench studies, the range of focus of the Precizon Go IOL is approximately **1.5D**.*

What is the range of vision of the Precizon Go? What is the add power, or to which add-power could it be compared with?

Precizon Go, as other Enhanced Intermediate Vision IOLs based on purely aspheric designs, does not have an optical addition. Instead, it is characterized by the so called **Range of Focus** or **Range of Vision**, which is defined as the range of distances with a visual acuity of at least 0,2LogMar. Such range of focus is measured in diopters.

Internal bench studies and measurements suggest that the range of focus of Precizon Go is approximately **1.5 D**. This range of focus would theoretically allow the patient to have vision up to **66 cm**. Clinical studies are currently being conducted in order to confirm the specific range of focus of the Precizon Go IOL.

Although the term addition can not be used for the Precizon Go IOL, its range of focus would offer vision up to the same distance than an IOL with an addition of 1.5 D (Fig. 4).

The doctor does not use / like hydrophilic IOLs!

There were issues with first generation of hydrophilic materials and production processes but Precizon lenses are hybrid and use hydrophobic monomers too. Keep an open mind to the extra benefits of the Precizon Go technology.

As recently published by Dr. Gerd Auffarth, hydrophilic acrylic IOLs play an important role in optimizing cataract surgery, with several advantages compared to hydrophobic IOLs. Among the most important advantages of hydrophilic acrylic materials we can highlight the following:

- Easy and quick unfolding, preventing rotation during surgery.
- Greater resistance to displacement or rotation as the capsular bag contracts.
- Their flexibility and compressibility make them an excellent choice for microincision cataract surgery, minimizing surgically induced astigmatism and improving the predictability of post-surgical unaided visual function.
- Highly biocompatible, a benefit for patients with uveitis or diabetes resulting in "quieter" eyes and excellent visual outcomes.
- Less light dispersion resulting in minimized chromatic aberration and glare.
- Less likely to develop glistenings, which can result in dysphotopsias, decreased contrast sensitivity, and other photic phenomena that interfere with vision.
- More resistant to forceps damage or fold marks.
- If necessary, rotating or explanting a hydrophilic IOL is easier than with hydrophobic acrylic IOLs.

For more information on Dr. Gerd Auffarth's publication please **click here**.

Precizon lenses have large haptics and doctors don't like them

Precizon haptics are designed to accommodate contraction of the anterior capsule up to 9 mm in diameter. This will avoid displacement of the optic forward or backwards, maintaining the effective lens position (ELP) and therefore minimizing the risk of residual refractive error.

Can Precizon Go and Precizon Presbyopic NVA coexist? Aren't they intended for the same target group / type of patients?

Precizon Go and Precizon Presbyopic NVA differ both on their design and their intended target group. In this sense:

- **Precizon Presbyopic NVA** is a p**resbyopia-correcting premium IOL** based on CTF technology designed for patients that seek for a **full range of vision** from distance to near.

- **Precizon Go** is a **standard cataract IOL** based on a modified aspheric optic and designed for standard cataract patients that desire a good distance vision and would also like to have a functional **enhanced intermediate vision.** Precizon Go does not provide near vision.

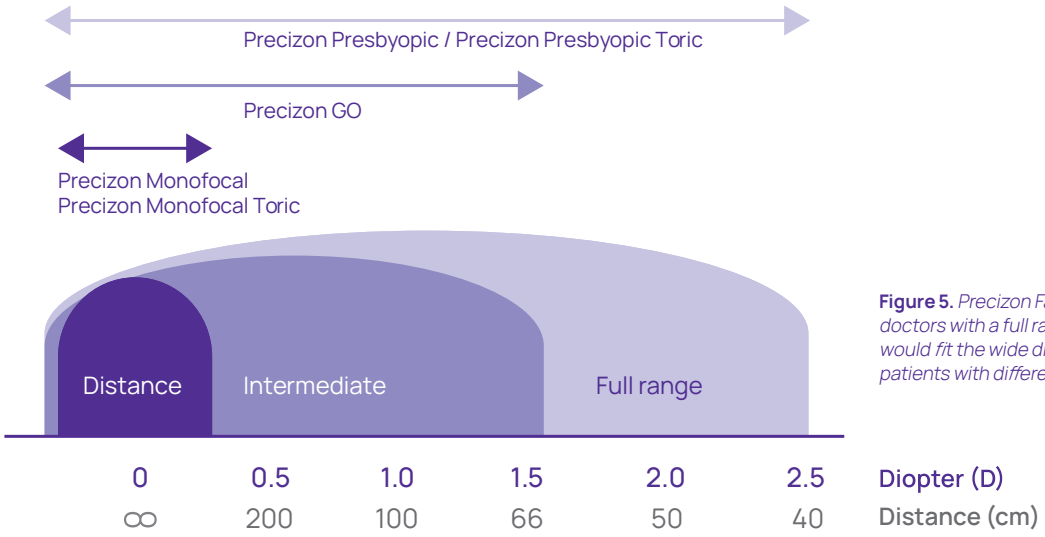

Figure 5. *Precizon Family now provides doctors with a full range of solutions that would fit the wide diversity of cataract patients with different demands.*

How does Precizon Go fit in with the existing range of Precizon Family IOLs?

Precizon Go completes the Precizon Family portfolio, allowing Ophtec to provide doctors with a full range of solutions that would fit the wide diversity of cataract patients with different demands. In this sense (Fig 5.):

- **Precizon Monofocal & Precizon Monofocal Toric** are the choice for standard cataract patients with no specific intermediate or near daily-life activities and demands, and with low finance possibilities.
- **Precizon Go** is the choice for **standard cataract patients** that would like to have a **wider range of vision** and functional spectacle independence not only for distance but also for some daily **intermediate** vision activities. They are not willing to accept the risk of a possible impairment in visual quality nor visual artifacts.
- **Precizon Presbyopic NVA & Precizon Presbyopic Toric** are the best choice for p**remium cataract patients** that demand a **full range of vision** from distance to near with excellent quality.

Is Precizon Go an Enhanced Monofocal or an EDOF IOL? Can we market Precizon Go as an EDOF IOL?

The ISO (International Organization for Standardization) and the AAO (American Academy of Ophthalmology) have defined specific standards and requirements for an IOL to be classified as an EDOF (Fig. 6). In this sense, EDOF IOLs must proof the following effectiveness requirements:

ISO	AAO
The mean, monocular photopic best corrected distance acuity shall be statistically non-inferior to the control using a non-inferiority margin of 0.1 logMAR	A minimum of 100 patients with EDOF lenses
The mean, monocular distance corrected photopic intermediate visual acuity at 66 cm shall be at least 0.2 logMAR	Depth of focus defined as the interval of nonpositive defocus values with a mean visual acuity of at least 0.2 logMAR
Average monocular defocus range at 0.2 logMAR shall be at least 0.5D greater than control	A depth of focus set at least 0.5 D wider than for the monofocal control group at 0.2 logMAR
Mean, monocular photopic distance corrected intermediate visual acuity at 66 cm shall demonstrate statistical superiority over the control group	Starting with CDVA, the IOL defocus range shall have a width of 1.5 D to less than 2.5 D, with defocus testing completed up to a minimum of -2.5 D

Figure 6. *ISO & AAO EDOF standards*

On the other hand, there are no official standards for the so called Enhanced Monofocal or Monofocal Plus IOLs.

Having said so, Precizon Go is an Enhanced Intermediate Vision IOL that provides extended range of vision from far to an intermediate distance up to approximately 66 cm. It is based on a modified aspheric design somehow similar to other IOLs that have been introduced in the market as Enhanced Monofocals, Premium Monofocals or Monofocal-EDOFs. Clinical evidence is still needed to confirm the performance of Precizon Go regarding visual acuity and defocus range outcomes, and to confirm if it meets the ISO standards for an EDOF IOL. In the meantime, the performance of the lens on existing bench studies and measurements suggest that Precizon Go could meet at least some of the abovementioned requirements.

What is the advantage of Precizon Go vs other Enhanced Intermediate Vision IOLs?

Precizon Go is an Enhanced Intermediate Vision (EIV) IOL characterized by a **unique and ingenious design**.
Such innovative design differentiates Precizon Go from other EIV IOLs providing the following advantages:

- **Outstanding vision quality** with no compromise or degradation at far nor intermediate distances.
- **Excellent tolerance** and easy neuroadaptation.
- **Minimum risk** of visual artifacts as **halos or glare**.

Which patients are suitable for Precizon Go? Can Precizon Go be implanted in all standard cataract patients like a monofocal IOL? When do I choose Precizon Go?

Precizon Go has been designed to be the first choice for any standard cataract patient. We can summarize the main indications for a Precizon Go IOL as follows:

- Standard cataract patients
- Patients that need excellent distance vision and would be happy to also have some intermediate vision.
- Patients with good ocular health.
- Myopic and hyperopic patients with corneal astigmatism < 0.75 D (else need the toric version; not available yet)
- Patients with neutral or positive spherical corneal aberrations.
- Calculated IOL power within available diopter range (-10 D to +35 D)
- Patients willing to accept and understand that will need spectacles for near vision tasks

When is Precizon Go contraindicated?

As with any other Enhanced Intermediate Vision IOL, Precizon Go should not be indicated in the following cases:

- Premium patients seeking for complete spectacle independency at all distances (far, intermediate and near).
- Extremely small pupil size (≤ 2 mm)
- Patients with pre-existing ocular pathologies or abnormalities which may be aggravated by the implant or that may predispose surgical complications as described on the IFU´s of the product.
- Use of medication that could have a negative impact on the outcome

Although not completely contraindicated, we must be careful with:

- Dry eye cases. They require treatment before assessment, IOL calculation and surgery

Is Precizon Go suitable for patients with ocular pathologies?

We hypothesize that the nondiffractive modified aspheric anterior surface and the continuous power profile of Precizon Go, which maintains good quality of vision and reduces photic phenomena, might be a potential reason for these IOLs to be suitable for patients suffering from ocular sight-threatening pathologies as macular degeneration, diabetic macular edema or some types of glaucoma, as long as such pathologies do not predispose surgical complications. However, clinical experience and evidence is needed to support such theory.

How does pupil size impact on the outcome of Precizon Go?

Precizon Go has been designed to provide good visual outcomes in different conditions, including different pupil sizes. Bench studies conducted up to date have tested the performance of the lens at far and intermediate distances for different aperture sizes such as 2.0, 3.0 and 4.0 mm. The results of such testings indicate that Precizon Go has a good performance on different pupil size conditions for both distance and intermediate vision. Clinical experience and evidence are currently been gathered to support these outcomes.

For pupil sizes lower than 2.0 mm Precizon Go would have a similar performance to Precizon monofocal. This means that patients with extremely low pupil sizes (< 2.0 mm) would not benefit from a Precizon Go IOL. These patients could experience however a slight increase on their depth of focus due to a pinhole effect.

Nevertheless, patients with such pupil apertures (< 2.0 mm) are extremely rare. Figure 7 shows the normal distribution of pupil size in the general population.*

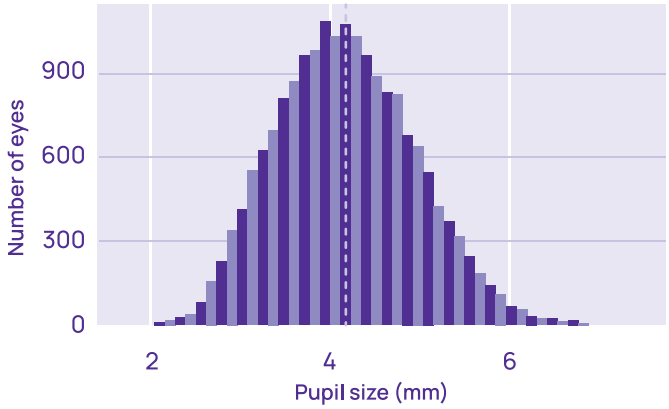

Figure 7. *Distribution of pupil size in the general population in Germany (the study included 18.335 eyes of subjects aged 40 to 80 years).*

** Marian Kiel et al. Distribution of Pupil Size and Associated Factors: Results from the Population- Based Gutenberg Health Study Sep 9;2022.*

How does preoperative corneal aberrations impact on the outcomes of Precizon Go?

Precizon Go has been designed to provide good visual outcomes in different conditions including presurgical corneal aberrations. Bench studies conducted up to date have tested the performance of the lens at far and intermediate distances for a wide range of corneal spherical aberrations going from 0 µ to +0.27 µ. The results of such testings indicate that Precizon Go has a good performance within such range of corneal aberrations for both distance and intermediate vision. Clinical experience and evidence are currently been gathered to support these outcomes.

How much spherical aberration (in microns) does Precizon GO induce to increase the depth of focus?

In order to increase the depth of focus, Precizon Go induces a positive spherical aberration by gradually shifting its power. As we can see on figure 1, Precizon Go gradually shifts its power from the base diopter reaching a maximum peak of +1.2D. In combination with the radial position this peak would correspond to an induced spherical aberration of **+0.53µm**.

How much corneal spherical aberration does Precizon Go compensate for?

The central part of the Precizon Go IOL is aberration neutral, as the Precizon Monofocal. However, the lens has a slight power drop at a radius of 1.5 mm from the center of the lens (see figure 1) which is partially compensating the corneal aberration. The maximum compensation peak corresponds to a spherical aberration of **-0.125 µm**, similar to Precizon Presbyopic NVA (-0.11µm).

Should we always target slight myopic outcomes?

We should aim for emmetropia. However, when calculations do not show a perfect emmetropia (0.00 D residual), we should aim for the nearest myopic diopter residual.

Is there a front and a back of the lens or can the IOL be implanted the wrong way round?

The Precizon Go IOL has a front and a back surface, and should be implanted correctly. However, accidentally implanting the IOL with the front surface towards the back should have a non-significant impact on vision.

Internal bench measurements have been done to analyze the impact of such event, concluding that it would result in a slight myopic shift of 0.1 D. Such amount of shift is well below any measuring tolerance, and should not have an impact on the visual acuity of the patient. .

What injectors and cartridges should we use for implantation?

Precizon Go is available in a semi-preloaded injector, called IOLMatic. It comes in an easy to use system with a 2.4 mm incision.

Can we guarantee that the lens will not get blurry / cloudy?

Blurriness or cloudiness of the lens is a very rare event that has only been seen with other Precizon IOLs in extremely cold temperature situations that result in a big difference between temperature of the lens and the surgery room. In such cases, a cold shock could occur resulting in cloudiness of the lens after extraction from the bottle or injection.

Therefore, in this extreme situation of temperature, we suggest making sure that the lens gets to room temperature before taking it out of the bottle.

In a rare event of cold shock, transparency of the lens gets restored after approximately 6 hours with no damage to its optics nor material.

What is the recommended CCC (Continuous Curvilinear Capsulorhexis) size on average when implanting a Precizon Go IOL?

Since the Precizon Go IOL has an optical zone of 6 mm, the recommended CCC is around 5 mm.

What near vision can patients achieve with Precizon Go? What is the reading distance with Precizon Go compared to Precizon Presbyopic?

Precizon Go is an Enhanced Intermediate Vision IOL that provides clear vision in a range that goes from far to an intermediate distance up to approximately 66 cm. Precizon Go is not designed to provide near vision, so it will not offer clear vision in the near range of 50 to 30 cm.

Precizon Presbyopic NVA is a presbyopia-correcting IOL that provides a **full range of vision** from distance to near up to 40 cm.

How does the defocus curve of the Precizon Go IOL look like? Is the Precizon Go defocus curve better than the ones with other Enhanced Intermediate Vision IOLs?

At this stage, clinical studies are being conducted in order to define the defocus curve of the Precizon Go IOL. In the meantime, the performance of lens on existing bench studies and measurements suggest that Precizon Go could have a range of focus of approximately **1 D to 1.5 D**.

Does Precizon Go IOL induce halos & glare? Can we take for granted that Precizon Go will induce no glare and halos?

Halos and glare are related to:

- diffractive or hybrid IOL designs that split the light to create 2-3 main focal points. They are caused by the out-of-focus rays of light that surround the main sharp focal points.
- some non-diffractive aspherical IOL designs with some kind of plateaus or transition zones on its surface.

Instead, Precizon Go is based on a purely non-diffractive aspheric design with a continuous and smooth power profile and surface; this means there are no rings, plateaus or transition zones whatsoever. These characteristics are intended for the Precizon Go to offer an extended range of vision with no visual artifacts as halos and glare. Clinical experience and evidence are currently been gathered to confirm such performance.

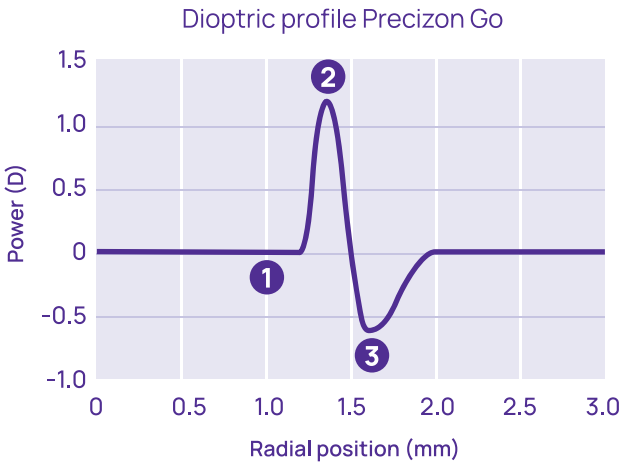

Figure 8. *Precizon Go is based on a purely non-diffractive aspheric design with a unique and ingenious power distribution. The figure shows the three main characteristics of the power profile of Precizon Go.*

How is the quality of vision and the loss of contrast sensitivity after implantating a Precizon Go IOL?

Degraded quality of vision, and therefore the loss of contrast sensitivity, is related to:

- aspherical designs with a relevant magnitude of spherical aberration, or
- diffractive hybrid designs due to the difference between the two images simultaneously projected on the retina.

Instead, Precizon Go is based on a purely non-diffractive aspheric design with some unique and ingenious characteristics that are specifically intended to maintain a good quality of vision after implantation. Such characteristics are (Fig. 8):

1. **Central optics** (2 mm) intended to maintain a good distance vision while proving intermediate vision.

2. **Power shift** at the mid-periphery of the lens, intended to boost intermediate vision and to avoid a relevant magnitude of spherical aberration that could cause a degraded image.

3. **Power drop** at 1.5 mm from the center of the lens, intended to compensate for the induced positive spherical aberration and therefore maintaining a good quality of vision.

All of these characteristics are intended for the Precizon Go to offer an extended range of vision with high image quality and no or minimal loss in contrast sensitivity. Bench studies conducted up to date confirm a good image quality; clinical experience and evidence are currently been gathered to confirm good quality of vision and levels of contrast sensitivity.

Can you achieve an acceptable near vision with Precizon Go when performing micro-monivision (-0.50D on non-dominant eye)?

Optically and theoretically speaking a micro-monovision with Precizon Go could be a good option to offer the patient a functional near vision in terms of quantity. However, clinical experience and evidence is needed to confirm the performance of Precizon Go with a monovision approach.

Additionally, we must keep in mind that a monovision correction can have an impact on binocularity, quality of vision and/or neuroadaptation. This risk must always be taken into account, no matter the type of lenses (ophthalmic, contact lenses and IOLs).

Is Precizon Go tolerant to misalignment, tilt or decentration?

Bench studies conducted up to date have tested the performance of the lens at both distance and intermediate vision for decentrations up to 0.5 mm. The results of such simulations indicate that Precizon Go is tolerant to decentration.

Clinical experience and evidence are currently been gathered to support such tolerance.

When assessing postoperative results after implantation of a Precizon Go IOL, how reliable is the autorefractemeter?

Autorefractors are not recommended to measure refractive error in eyes implanted with IOLs different from a standard monofocals. Autorefractometers are calibrated to measure the refractive error in natural healthy eyes with natural optics, and they use the central part of the pupil to estimate refraction.
Any irregularity or non-standard power profiles in any of the optical surfaces of the natural eye or the artificial implanted IOLs will lead to an unreliable measurement. This is what happens with dry eyes, keratoconus, and also in eyes implanted with any IOL with modified power profiles and surfaces (this includes all types of Enhanced Intermediate Vision IOLs and presbyopia-correcting IOLs).

In the specific case of the Precizon Go IOL, autorefractors might not be able to capture the continuous power progression on the anterior surface of the lens. Therefore, they might not provide optimal postoperative refraction in patients implanted with this technology.

Standard subjective refraction is **recommended** to measure the postoperative refractive status of the patient after implantation of Precizon Go, or any other kind of Enhanced Intermediate Vision IOL.

How much adjustment time does the patient need on average after a Precizon Go IOL has been implanted?

After any cataract surgery, the adaptation process varies from patient to patient. It is also related to a correct preoperative indication and expectations management. In addition, patient's satisfaction is very subjective.

The smooth and continuous power profile of the Precizon Go IOL suggests an easier neuroadaptation process compared to diffractive / hybrid Enhanced Intermediate Vision IOLs and also to multifocal IOLs. In contrast, it should be similar to the monofocal IOL, with a very low adjustment period. Clinical experience and evidence are currently been gathered to support this theory.