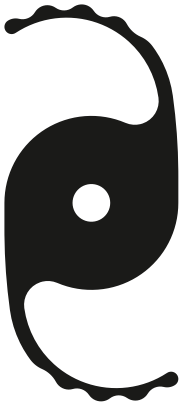
XtraFocus

INTRAOCULAR PINHOLE IMPLANT



MADE IN GERMANY

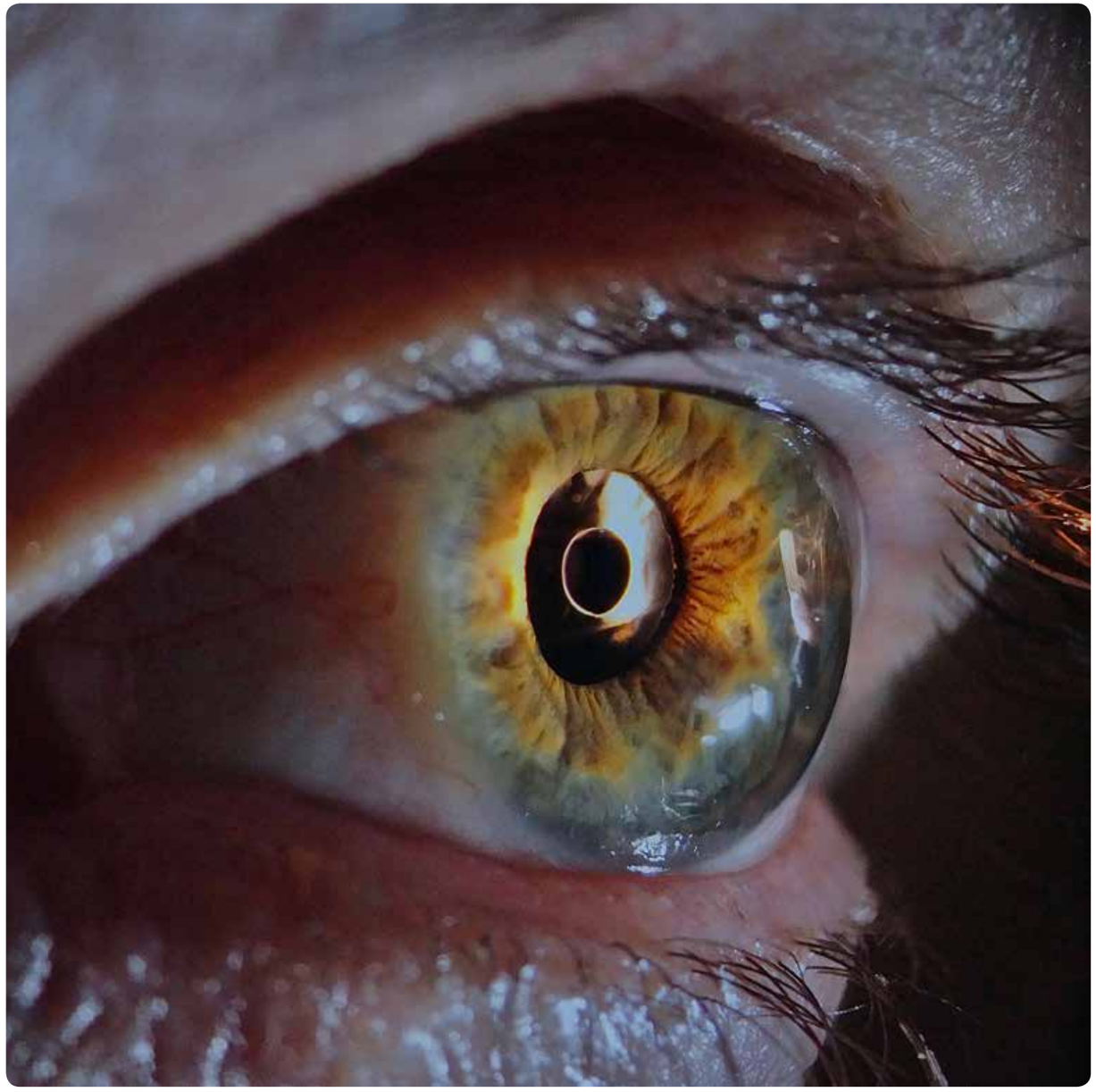
THE XTRAFOCUS IS AN ELEGANT SOLUTION TO COMPLEX CASES.

Based on the well-established principle of pinhole optics, this intraocular implant represents an innovative alternative for the ophthalmic surgeon.

The following pages will provide detailed information required for safe and effective use of the XtraFocus Pinhole Implant.

Camera Obscura, Perdika (Greece)

CONTENT



OVERVIEW

Dr. Claudio Trindade

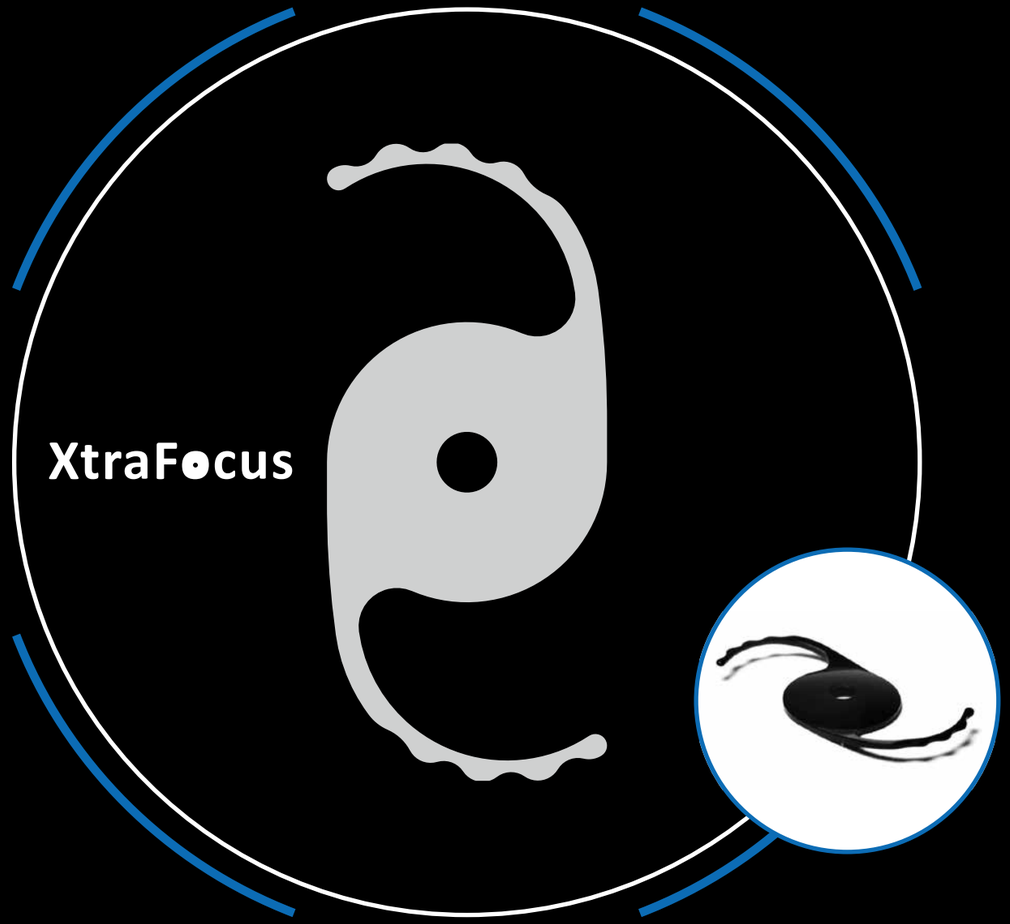
The **XtraFocus Pinhole Implant** is a pinhole intraocular implant. It has a 6.0 mm occlusive portion with a 1.3 mm pinhole aperture, with **no dioptric power**.

It was conceived for the treatment of **irregular corneal astigmatism** with additional secondary indications.

The pinhole aperture is able to **effectively minimize** the impact of corneal aberrations on the image quality.

With two angulated open-loop haptics, it is designed to be implanted in the **cilliary sulcus** of pseudophakic eyes, in a **piggyback** configuration.

Attention: The XtraFocus should not be implanted in phakic patients.



TECHNICAL SPECIFICATIONS

TOTAL DIAMETER	14.0 mm
PINHOLE DIAMETER	1.3 mm
OPTIC DIAMETER	6.0 mm (concave-convex / no refractive power)
POSITION	Sulcus
HAPTIC	2 Open-Loop | 14° (250 micron)
MATERIAL	BLACK Hydrophobic Acrylic
WATER CONTENT	< 0.5 %
INJECTOR (RECOMMENDATIONS)	Alcon Monarch III with D cartridge Medicel VISCOJECT™-BIO 2.2

FOUR SPECIFIC FEATURES TO PREVENT UVEITIS-GLAUCOMA-HYPHEMA SYNDROME (UGH)

- larger overall diameter (14.0 mm)
- 14° angulated haptics
- thin haptics (250 micron)
- rounded and polished edges of haptics and occlusive portion

INDICATIONS

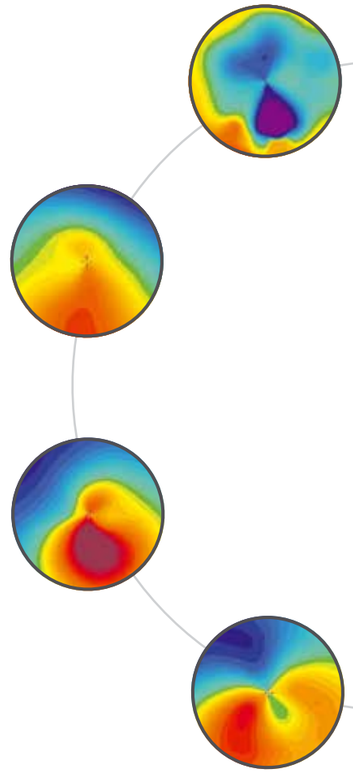
The main indication for the XtraFocus Pinhole Implant is the **treatment of irregular corneal astigmatism (ICA).**

This includes

- Keratoconus
- Pellucid Marginal Degeneration
- Post-Radial Keratotomy ICA
- Post-Penetrating Keratoplasty ICA
- Post-LASIK Ectasia
- Traumatic corneal laceration

Secondary indications are

- **Near Vision** Enhancement in **Monofocal Pseudophakia** (Depth of Focus Extension)
- Reduction of **Dysphotopsias** in **Multifocal Pseudophakia** (Halos and Glare)



PREOPERATIVE EVALUATION

The preoperative evaluation is simple and does not require any special equipment. However, some important tests should be performed.

The indication is based on FOUR main parameters:

1. PINHOLE ACUITY TEST

Consider a good candidate if there is a **solid** and **reliable** improvement when the pinhole is placed **on top of the best refraction.**

If the patient requires excessive time and effort to achieve improvement during the test, the XtraFocus implantation might not render a good visual result. This is usually observed in extremely irregular corneas.

Even with a favourable pinhole acuity test, **central** corneal opacities (corneal dystrophies, scars, severe haze, etc.) represent a relative contraindication for this treatment.

2. CORNEAL TOPOGRAPHY

Avoid **extremely** irregular corneas, such as

- Keratoconus with K readings above 60.0 D
- Radial Keratotomy with multiple intersecting incisions and K readings below 28.0 D.
- The clinical benefits of the XtraFocus are limited by the amount of high order aberration. Patients with severe topographic irregularity and / or central corneal opacities may not achieve sufficient improvement in visual acuity with this treatment.
  In those cases, other corneal treatments (including a corneal graft) may be necessary.

3. PUPILOMETRY

Consider a good candidate if the pupil diameter is 3.0 mm or larger in mesopic conditions.
The larger the pupil, the greater the benefit of implantation.

4. REFRACTION

Consider a good candidate someone with a moderate myopic refraction (approx. - 2.0 D). This will result in a very solid near vision with reasonable distance vision, which can be improved with glasses post-operatively.

Although subjective refraction is challenging in cases of irregular corneal astigmatism, this is a very important point to be considered.

If the implantation of the XtraFocus is being considered during cataract surgery, a - 2.0 D target is advisable.

PREOPERATIVE RETINAL EVALUATION

Implantation of the XtraFocus Pinhole Implant makes fundus examination more difficult. Therefore, it is mandatory to perform a thorough posterior segment examination, including binocular indirect ophthalmoscopy with scleral indentation, before the implantation of the device.

Any retinal pathology should be treated before implantation and risk factors for retinal disease (especially those conditions that affect the peripheral retina) should be considered in the preoperative evaluation. If any vitreoretinal treatment is needed after implantation, the device would have to be explanted.

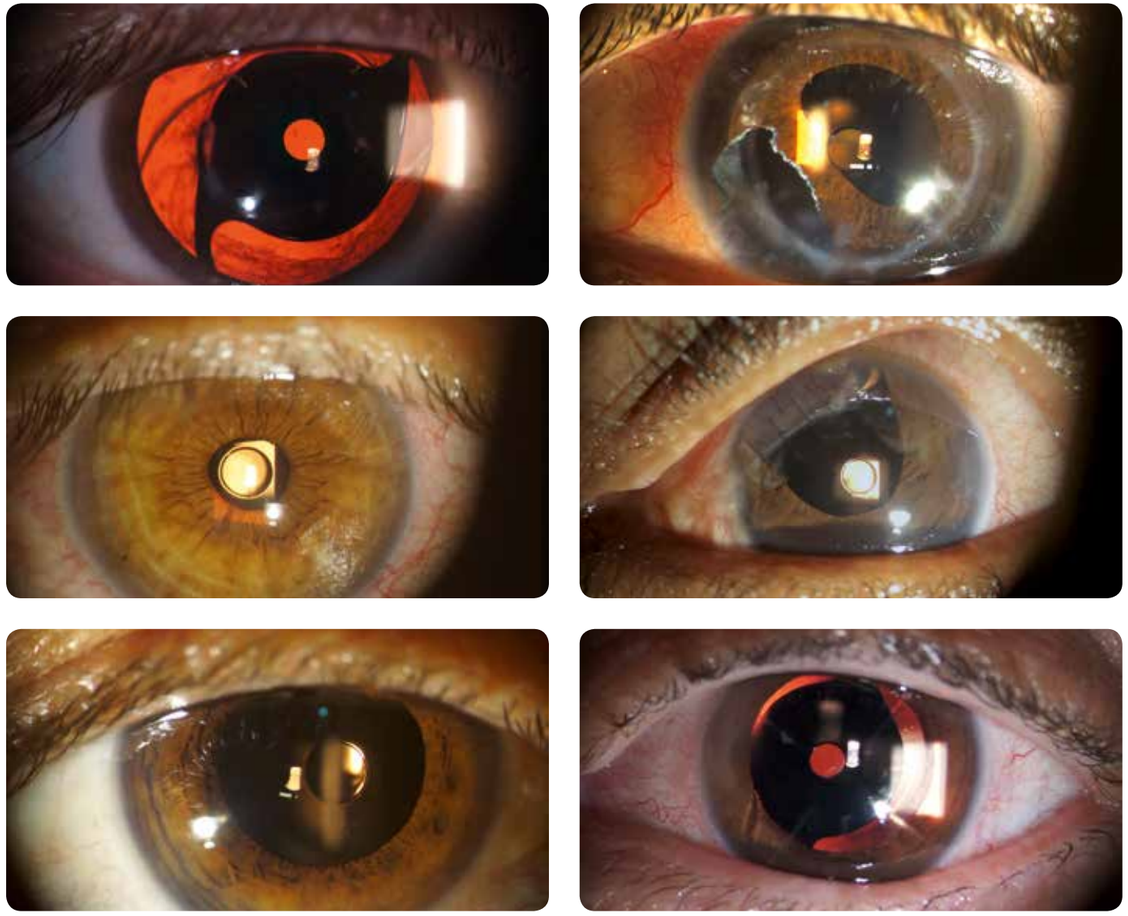
See the postoperative follow-up section for more detailed information.

SURGICAL PROCEDURE

- Routine steps for posterior chamber IOL implantation, through a 2.2 mm corneal incision.
- The XtraFocus Pinhole Implant can be implanted with most commercially available IOL delivery systems.
- **The device should not be implanted upside down.** To ensure proper orientation, the leading haptic should be directed to the left during implantation.
- Care should be taken to achieve proper centration of the intraocular implant.

  A subtle decentration towards the nasal portion of the pupillary area is advisable. Rotation of the implant may help achieving the targeted position.
- In case of primary piggyback implantation (concomitant with cataract surgery) it is advisable to remove OVD from the capsular bag after in-the-bag IOL implantation, to avoid unintentional placement of the XtraFocus inside the capsular bag.

There is no need to perform peripheral iridectomy, since the pinhole aperture allows for adequate aqueous flow.



POSTOPERATIVE FOLLOW-UP

A conventional cataract surgery follow-up regimen should be adopted. A few important details should be observed:

AUTOREFRACTION

Autorefraction readings are not reliable after implantation of the XtraFocus.

A false hyperopic shift is observed after implantation. Since the black material of the XtraFocus is transparent to infrared light (see page 17) the infrared light emitted by the auto refractor is affected by the negative meniscus shape of the XtraFocus, generating a false hyperopic shift. This reading should be ignored.

SUBJECTIVE REFRACTION

Because of the Depth of Focus Extension caused by the XtraFocus implantation, changes during subjective refraction becomes less evident to the patient. Therefore larger dioptric steps (two or more diopters) should be considered by the examiner.

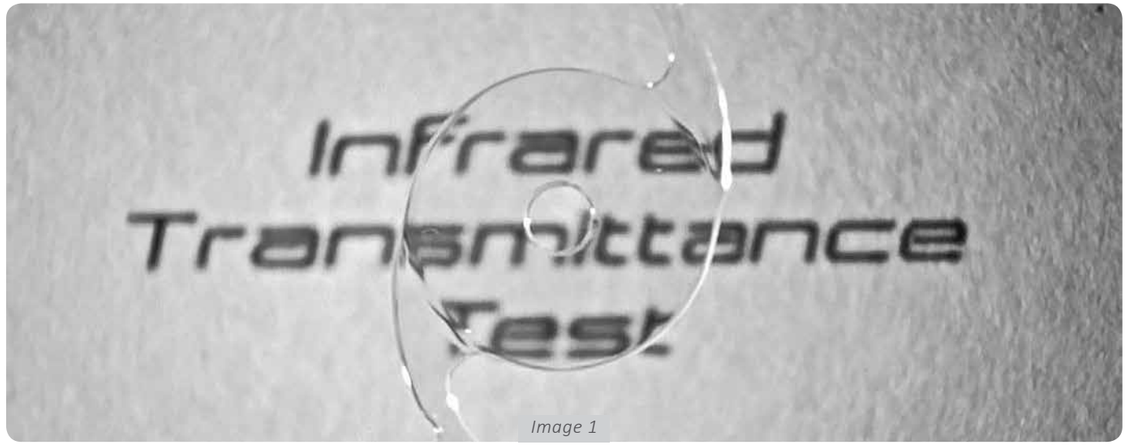


Image 1

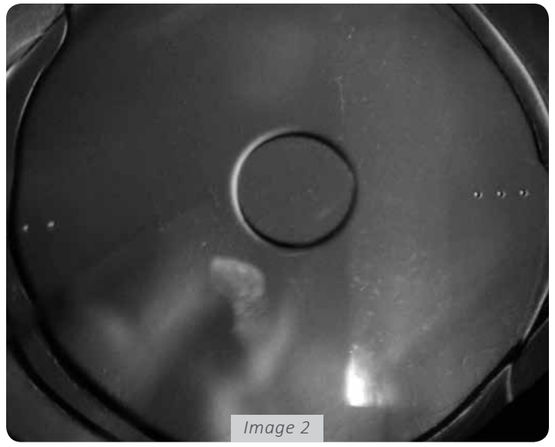


Image 2

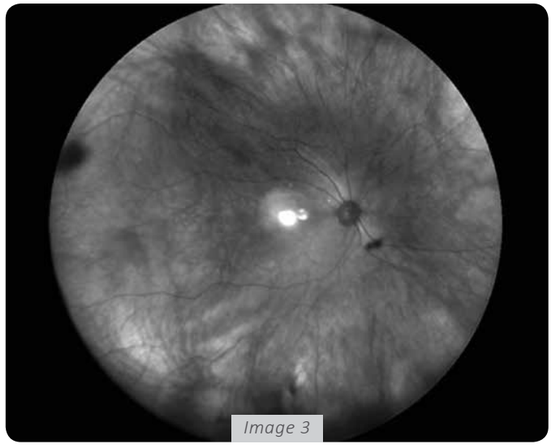


Image 3

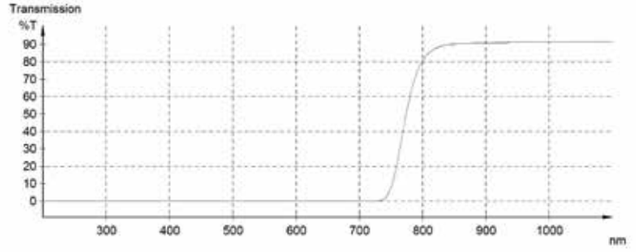
POSTOPERATIVE FOLLOW-UP

RETINAL EXAMINATION

The ability to perform binocular indirect ophthalmoscopy and some treatments (e.g. retinal photocoagulation, pars plana vitrectomy) is limited after implantation of the XtraFocus Implant.

To overcome this limitation the black acrylic has the unique feature of being transparent to infrared light (images 1 and 2)

Examination of the posterior segment is possible with Infrared-based imaging equipment such as OCTs and scanning laser ophthalmoscopes. With special lenses (scanning laser ophthalmoscope contact lens or a non-contact ultra-wide-field lens), the field of view can be expanded to 150 degrees (image 3). For wider examination of the peripheral retina a B-Mode Ultrasound may be necessary.



FREQUENTLY ASKED QUESTIONS

DO PATIENTS REPORT REDUCTION OF LUMINANCE?

Because of the restriction of light entrance imposed by the pinhole aperture, a sensation of darkened vision may be reported after implantation. This finding may vary in intensity and is normlly well-tolerated. Patients with greater magnitude of corneal irregularity typically do not report this condition. Patients with normal corneas usually report this symptom with greater intensity.

Mild visual effects associated with a XtraFocus Pinhole Implant may occur. These may include a perception of halos around lights under nighttime conditions.

CAN YAG CAPSULOTOMY BE PERFORMED AFTER THE IMPLANTATION?

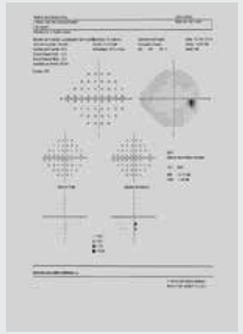
It is absolutely possible to perform YAG capsulotomy after the implantation. It is even possible to extend the capsular opening beyond the margins of the pinhole by asking the patient to look sideways.

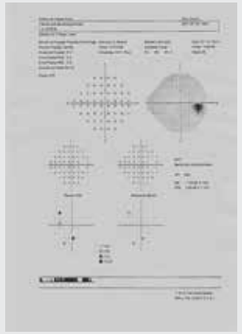
However, in very irregular corneas it may be challenging to aim accurately because of light reflections, which can lead to some pits in the IOL.

It is not recommended to perform a prophylactic capsulotomy, prior to implantation.

DOES IT CAUSE VISUAL FIELD CONSTRICTION?

No, as long as the XtraFocus Pinhole Implant is well-centered, it does not cause constriction of the visual field. This is because of the close proximity between the implant and the iris plane. However, it does cause a slight reduction in overall retinal sensitivity, which can be observed in automated perimetry.





WHICH IOL TO CONSIDER WHEN PLANNING FOR XTRAFOCUS IMPLANTATION DURING CATARACT SURGERY?

Any monofocal IOL can be used (spherical, aspherical, toric, non-toric). It is very important to plan for a refractive target of approximately - 2.0 D. This will result in a very solid near vision with reasonable distance vision, which can be improved with glasses postoperatively.

HOW TO MANAGE CENTRATION?

During surgery, a minor decentration towards the nasal portion of the pupillary area is advisable. A vertical orientation of the haptics is recommended, to allow for easier lateral adjustment of the XtraFocus. Rotation of the implant may help achieving the targeted position.

As expected with any sulcus fixated implant, minor decentrations may occur over time, especially in larger eyes. Slight decentrations are usually asymptomatic. Larger decentrations may cause reduction in visual acuity. Rotation of the device under peribulbar block is advisable to restore proper position. Re-expansion of the anterior capsular rim, followed by optic capture of the XtraFocus will ensure a more secure position (depending on size and position of the capsulorhexis).

WHEN SHOULD I CONSIDER A TORIC IOL WITH THE XTRAFOCUS?

The pinhole aperture is able no minimize high order aberrations and low order aberrations, including astigmatism. However, this effect is limited to a certain extent. In cases of astigmatism of greater magnitude, presenting a more regular bow tie, a toric IOL might be an interesting option. This decision should be based on the pinhole acuity test, adding cylindrical correction on top of the pinhole. If there is significant improvement of visual acuity, a toric IOL may be considered.

ARE THERE DIFFERENT VERSIONS AVAILABLE, WITH VARIED DIMENSIONS?

No, there is only one version of the XtraFocus. With an overall diameter of 14.0 mm and flexible haptics, it was designed to adjust to various ciliary sulcus dimensions, ith a gentle pressure in the sulcus.

CAN THE XTRAFOCUS BE IMPLANTED INSIDE THE CAPSULAR BAG?

Yes. Although the XtraFocus Pinhole Implant was designed for sulcus implantation, it may also be implanted inside the capsular bag (with or without a primary IOL). A "solitary" in-the-bag implantation of the XtraFocus (without a primary IOL) may be considered in cases of keratoconus, when a near-plano IOL is suggested during IOL power calculation.

IS IT AVAILABLE WITH DIOPTRIC POWER?

No, the XtraFocus is a pinhole intraocular diaphragm, with no refractive power.

LITERATURE

New pinhole sulcus implant for the correction of irregular corneal astigmatism

Claudio C. Trindade, MD, Bruno C. Trindade, MD, Fernando C. Trindade, MD, PhD, Liliana Werner, MD, PhD, Robert Osher, MD, Marcony R. Santhiago, MD, PhD
Journal Of Cataract Refractive Surgery, VOL 43, Issue 10, October 2017

Novel pinhole intraocular implant for the treatment of irregular corneal astigmatism and severe light sensitivity after penetrating keratoplasty

Claudio L.C. Trindade, MD, Bruno L.C. Trindade, MD
JCRS Online Case Reports, VOL 3, January 2015

Phacoemulsification with intraocular pinhole implantation associated with Descemet membrane endothelial keratoplasty to treat failed full-thickness graft with dense cataract

Bruno Lovaglio Cançado Trindade, MD, PhD, Fernando Cançado Trindade, MD, PhD, Claudio Lovaglio Cançado Trindade, MD, Marcony Santhiago, MD, PhD
Journal of Cataract and Refractive Surgery

Assessment of a novel pinhole supplementary implant for sulcus fixation in pseudophakic cadaver eyes

Eye, October 2017

The Lowdown on High-Tech IOLs

EyeNet, October 2017

New Intraocular Lenses

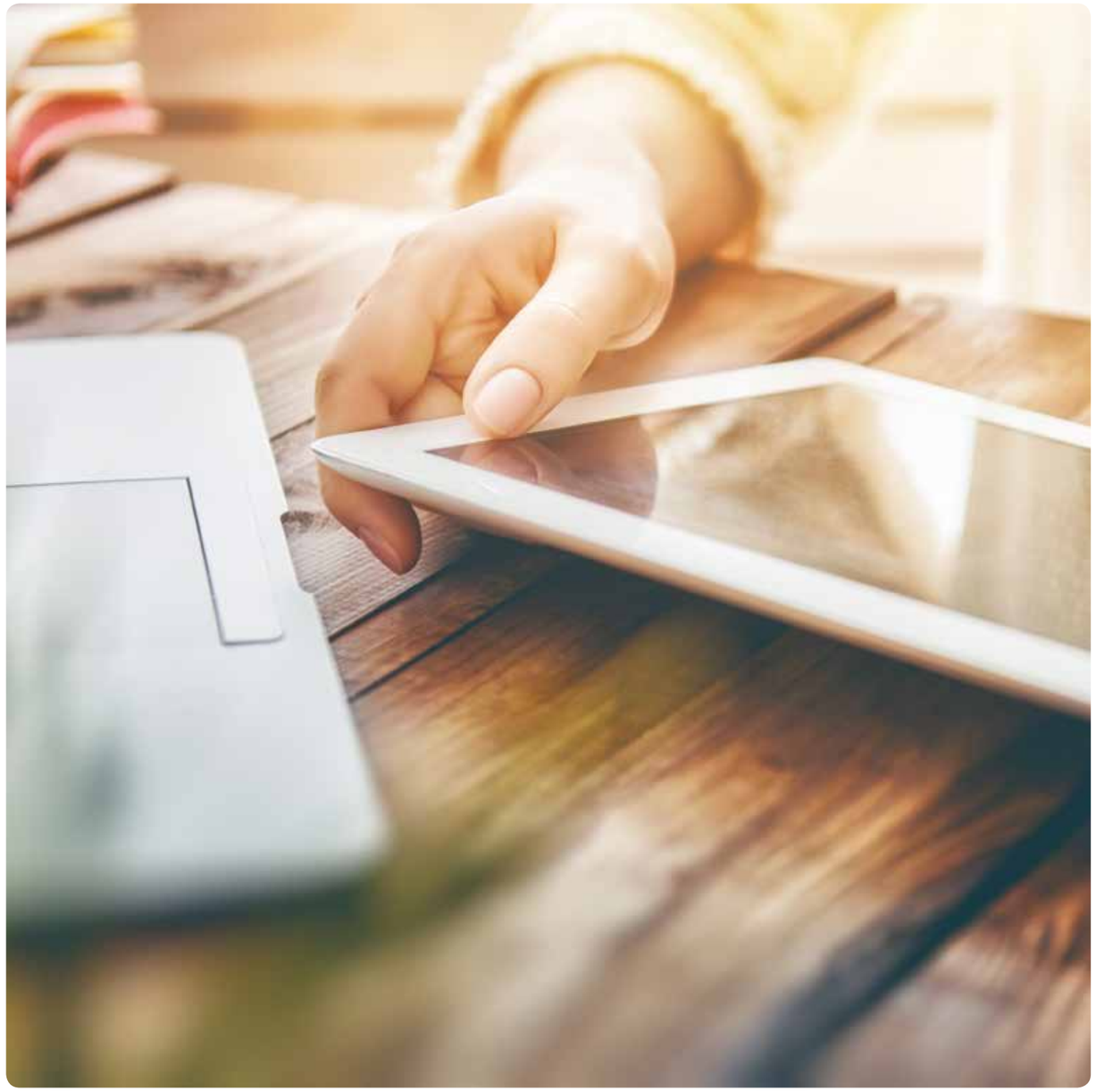
EuroTimes, February 2018

Development of a pinhole implant: XtraFocus

Claudio C. Trindade, MD
Cataract and Refractive Surgery Today Europe, February 2016

A Small-Aperture intraocular diaphragm

Claudio C. Trindade, MD
Cataract and Refractive Surgery Today Europe, January 2015



VIDEO GALLERY

- Tiny Hero Against the Evil Axis
  ASCRS Film Festival Grand Prize 2017
- XtraFocus Pinhole for Keratoconus
- XtraFocus Pinhole for Mydriasis and RK Irregular Astigmatism
- XtraFocus Pinhole for Keratoconus and Mydriasis
- XtraFocus Pinhole for Penetrating Ocular Trauma
- XtraFocus Pinhole for Irregular Astigmatism after RK
- XtraFocus Pinhole for Keratoconus

You will find all listed videos on our website www.morcher.com

MORCHER® GmbH

Kapuzinerweg 12
70374 Stuttgart
GERMANY

Phone +49 (0) 711 / 95 320 - 0
Fax +49 (0) 711 / 95 320 - 80

E-Mail info@morcher.com
Web **www.morcher.com**

V2018-08 / BAR