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PATIENT INFORMATION BROCHURE*

Zaracom Hydrophobic Acrylic Monofocal/Multifocal Intraocular Lens (IOL)

**To Accompany Patient Lens Implant Card*













This encompasses all foldable posterior chamber intraocular lenses produced under the ZARACCOM trademark, including Domicryl, TruSmart, and FOCUSforce Basic.

NOTE to Physician: Please remove the label from provided in the IOL box. Place this label on this brochure, which includes the following information: device name, serial number, lot number, UDI, and device model.

PATIENT INFORMATION BROCHURE

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Glossary for the Symbols and Abbreviations in this Brochure or on Implant Card

Symbol / Abbreviation	Definition	Symbol / Abbreviation	Definition
	<i>Manufacturer</i>		<i>Serial Number</i>
	<i>Unique device identification</i>		<i>Date of manufacture</i>
	<i>Patient information website</i>		<i>Consult instructions for use (Note: This is for your doctor)</i>
$\emptyset B$	<i>IOL Optic (central, round part of IOL) diameter</i>	$\emptyset T$	<i>Overall IOL diameter including haptics (arm-like structures attached to optic)</i>
IOL	<i>Intraocular Lens</i>		<i>Date of Surgery</i>
	<i>Patient identification (Person receiving medical treatment)</i>		<i>Health care centre or doctor (Doctor doing surgery)</i>
	<i>Hospital (Place where surgery was done)</i>	Dpt.	<i>IOL Power</i>
	<i>Model number</i>		<i>Use by date</i>

GENERAL INFORMATION ABOUT IOLs AND IOL IMPLANTATION SURGERY

What is an intraocular lens (IOL)?

An intraocular lens, also called an IOL, is an artificial lens made with an acrylic material that is implanted in the eye to replace the natural lens after it is removed. IOLs generally have two basic features:

- The optic portion is the round part of the IOL, which focuses an image onto the back of your eye (retina).
- Haptics are two arm-like structures attached to the optic, which maintain the IOL position in the eye.

Why is the natural lens of the eye replaced?

The natural lens in your eye focuses images onto the back of your eye so you can see clearly, like a camera lens focuses images to create a clear picture. At birth, your natural lens is clear. With age, the lens may become “cloudy.” A cloudy lens is called a cataract and is usually due to natural aging. As the lens becomes cloudier, your quality of vision may decrease. A cataract can progress until there is a complete loss of vision in your eye. Surgery is the only way to remove a cataract. You may have had surgery to replace your natural lens before it became a cataract so that you could decrease your dependence on glasses.

What is the possible diagnostic or therapeutic alternatives?

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

The only effective treatment is surgery, that is removal of the clouded lens followed by IOL implantation.

Intraocular lens implantation is called a routine practice in the literature, since its optical advantages and complications are very low. Small incision size cataract surgery technique has been developed to reduce post-operative astigmatism and patient rehabilitation time. An intraocular lens is placed in the capsule to replace the explanted natural lens.

Zaracom Monofocal Intraocular Lenses

The Zaracom IOL is designed to reduce the need to wear glasses for distance vision after your surgery. You will be able to see objects far away. However, you will most likely need glasses for:

- near distance activities, such as reading
- intermediate distance activities, such as working on a computer.

Zaracom Multifocal Intraocular Lenses

ZARACCOM multifocal intraocular lenses are intended for patients who need near and distance vision and who desire an independent field of vision from spectacle. The intraocular lens is designed to increase the spectacle independency for both distance and near vision.

IOLs, like the Zaracom IOL, have been the standard eye implant used after a natural lens is removed. There are several different types of Zaracom IOLs. Your patient implant card will tell you which IOL you received.

Zaracom IOLs have been implanted in more than 7 million eyes since 2006. Based on required testing of the Zaracom material, Zaracom IOLs are expected to be stable in the eye over your lifetime. The IOL will remain in your eye after implantation and will not be removed unless your doctor recommends it.

SAFETY INFORMATION FOR ZARACCOM IOLs AND IOL IMPLANTATION SURGERY

RESIDUAL RISKS, UNDESIRABLE EFFECTS AND WARNINGS

As with any surgery, there is risk involved whether or not an IOL is implanted. Potential complications accompanying cataract or implant surgery are not limited to the complications listed below. Cataract surgery, with or without lens implantation might be associated with:

- Ocular inflammation
- Hemorrhage
- Intraocular pressure elevation
- Post-operative infection
- Retinal breaks and detachment
- Cystoid macular edema
- Corneal edema
- Posterior capsule opacity

Complications related with Intraocular Lens implantation:

- Capsular rupture
- Vitreous loss
- Lens decentration and luxation
- Wrong calculation of IOL power
- Damage of IOL during implantation

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

Contact your eye doctor immediately if you have any of these symptoms after surgery:

- Significant decrease in vision
- Significant eye pain
- Significant itching of the eye
- Significant redness of the eye
- Watering of the eye
- Double vision lasting more than a few days
- Significant eye discharge
- Increased sensitivity to light

These symptoms could indicate potential serious postoperative complications, and you should follow up with your eye doctor.

Postoperative Care Instructions

Your eye doctor will give you eye drops to speed up the healing process and to prevent infection. Your eye doctor will tell you when to return for a medical visit(s) to monitor your eye after surgery.

Many patients may see better within 1 to 2 weeks or less. The specifics of surgery may be different for each individual. Talk with your eye doctor so you can understand the recovery process after surgery.

Long Term Considerations

Keep the patient lens implant card provided by your eye doctor as it has important information about the IOL implanted in your eye. Also, the patient lens implant card has the website where you can print this patient information brochure, including any recent updates to this brochure. The patient brochure is available electronically at www.anadolutip.com.tr

If you experience a health issue related to your Zaracom IOL, have your patient lens implant card available, and take the following steps:

- Consult your eye doctor.
- Ask your eye doctor to report the health issue as described in the Zaracom IOL instructions for use when your health issue could be related to the implanted intraocular lens.

Magnetic Resonance (MR) Safe

Zaracom IOL is MR-Safe as this implant is made of an acrylic (plastic) material that does not conduct electricity, contains no metal, and is not magnetic. Thus, the implant in your eye poses no known hazards in magnetic resonance (MR) imaging environments. There is no risk to you if you have MR testing done with the IOL implanted in your eye.

SUMMARY

The Zaracom Monofocal IOL is designed to reduce the need to wear glasses for distance vision after your surgery. Zaracom Multifocal IOL is designed to reduce the need to wear glasses for near and distance vision after your surgery. Always consult with your eye doctor if you have any questions or concerns.

Additional information about Zaracom IOLs can be found in a document called "Summary of safety and clinical performance" or SSCP and associated with the device's basic UDI. Once the website is live, this document will be available at <https://ec.europa.eu/tools/eudamed>



ANADOLU TIP TEKNOLOJİLERİ ÜRETİM PAZARLAMA İTHALAT İHRACAT TİCARET VE SANAYİ ANONİM ŞİRKETİ

1.Organize Sanayi Bölgesi 2. Kısım 5. Cad. No:10 Merkez, Sivas, Türkiye

Tel. +90 346 218 14 18 (pbx)

Fax.+90 346 218 14 20

www.anadolutip.com.tr

info@anadolutip.com.tr