www.anadolutip.com.tr

ZARACCOM LENSES **ASP-03/2023-RV 00**

Foldable Aspheric Preloaded Intraocular Lens Instruction For Use
Zaraccom Aspheric (AS60125P) and Zaraccom Aspheric L (AS60130P)

EN

DESCRIPTION: Zaraccom foldable aspheric preloaded intraocular lenses (IOLs) are designed for cataract surgery as an anterior surface aspheric optic device to replace the crystalline lens and to reduce the spherical aberration in the human eye. Foldable IOLs consist of hydrophobic acrylic and are manufactured with bonded UV-absorber, are sterile, 1-piece and suitable for posterior chamber implantation. They have a biconvex optic with supporting haptics.

MATERIAL DESCRIPTION: The foldable hydrophobic acrylic IOLs, referred to as acrylic origin chemical structure which consists of 80% olugo urethane acrylate with phenoxyethyl methacrylate, octyl methacrylate, methacrylic acid and benzotriazole.

Table1. Physical Characteristic of IOLs

Physical Characteristic	**Description**
Models	AS60125P and AS60130P
Material	Hydrophobic Acrylic (Acrylate-Methacrylate Copolymer)
Index of Refraction	1.51
Optical Design	Aspheric, Bi Convex, square edge
YAG Laser	Stable
Sterilization Type	Ethylene Oxide
Power	+5 through +30 Dpt (0.50 Dpt increments)
Estimated A. Constant (Calculated theoretically)	118.4
Haptic Angle	0°
Haptic Configuration	Modified L-Loop
Water Content	<1%

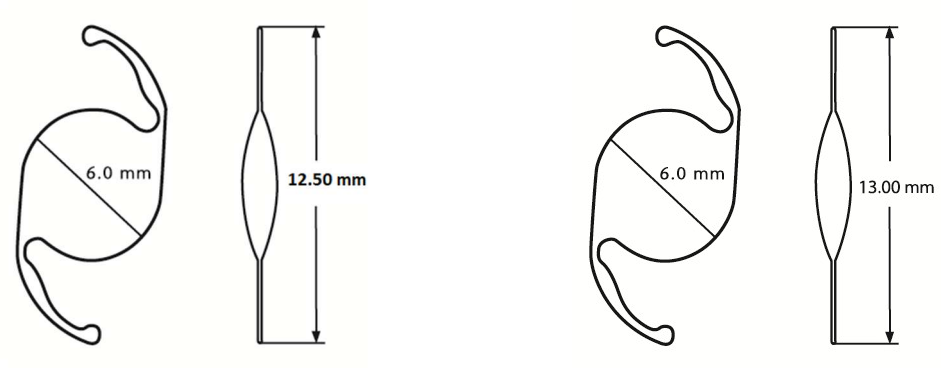
Foldable aspheric preloaded intraocular lenses are supplied with a disposable sterile injector system. The injector system is made of high-quality materials and has been designed exclusively for foldable intraocular lens (IOL) implantation. The injector system allows the ophthalmic surgeon to safely inject Zaraccom preloaded intraocular lenses, into the eye through ≤2.2 mm incisions.

MATERIAL COMPONENTS FOR PRELOADED INJECTOR SYSTEM:

1. Injector Body: Methyl methacrylate
2. Plunger: Acetal copolymer
3. Silicone Cushion: Silicone
4. Spring: Stainless steel
5. Cartridge: Polypropylene
6. Folding Element: Polypropylene
7. Blister material: pet, cover material: tyvek

Figure 1: Design of Zaraccom IOL Models

Model AS60125P **Model AS60130P**



BIOCOMPATIBILITY TESTING

Potential patient safety risks to the material(s) of this device were evaluated through nonclinical physicochemical characterization and biocompatibility testing in accordance with international standards applicable to IOL devices. Nonclinical testing demonstrated no safety concerns for local or systemic toxicity, that the IOL material was physically and optically stable, and that there were no leachable substances arising from the manufacturing process (including sterilization) or device material(s) that posed a safety risk. The device possesses an acceptable patient safety profile when used in accordance with the Instruction for Use (IFU) for its intended clinical purpose as an ocular implant device.

MODE OF ACTION

Intraocular lens implantation is called a routine practice in the literature, since its optical advantages and complications are very low. Small incision cataract surgery technique has been developed to reduce post-operative astigmatism and patient rehabilitation time. These lenses are used by a trained ophthalmic surgeon and placed in the posterior chamber of the eye instead of the natural crystalline lens. In this position, the lens corrects vision by functioning as a refractive medium in aphakia correction. Achieving the device's intended mode of action is achieved by cataract surgery with the implantation of an artificial lens instead of the natural lens of the eye.

Product user group : Ophthalmologists
Patient population : Adult aphakia patients

INTENDED USE

Zaraccom posterior chamber intraocular lenses are intended for use by a trained ophthalmic surgeon. The IOL is intended to be positioned in the posterior chamber of the eye, replacing the natural crystalline lens. This position allows the lens to function as a refractive medium in the correction of aphakia. These lenses are intended for placement in the capsular bag.

INDICATIONS

Zaraccom foldable posterior chamber IOLs are indicated for primary implantation for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed.

CONTRAINDICATIONS

To date there are no absolute contraindications to Intraocular Lenses implantation. There are no known contraindications with the use of Zaraccom IOL when used as recommended.

RESIDUAL RISKS AND UNDESIRABLE EFFECTS

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

WARNINGS AND PRECAUTIONS

- A high level of surgical skill is required for intraocular lens implantation. The surgeon should have observed and/or assisted in numerous implantations and successfully completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
- Prior to surgery, prospective patients should be informed of the possible risks and benefits associated with this IOL as well as the risks and benefits associated with cataract surgery. After surgery, physicians should provide an information brochure to patients regarding the IOL implanted (located at www.anadolutip.com.tr) along with the implant card.
- Do not use the intraocular lens in case the sterile package was opened or damaged or in any case of doubt.
- Do not use the intraocular lens after expiration date.
- Do not resterilize this intraocular lens by any method.
- Do not reuse the lens. Single use only. The lens must be used once only for a single patient. Reuse of this single-use device may result in serious injury, such as endophthalmitis.
- Do not store at under 5°C (41°F) and above 35˚C (95˚F). The manufacturer recommends the storage and usage of lenses at room temperature (This allows the intraocular lens to open more slowly in the capsule). Do not expose the lens to sunlight.

- Do not soak the lens and injector system in solutions other than balanced saline solutions or equivalents.
- This lens and injector system is used safely with viscoelastic materials (OVD). As a manufacturer, it is recommended to use an OVD with a density of 1.4% / 1.6% / 1.8%.
- Handle the lens carefully to avoid damage to lens surfaces or haptics.
- Do not attempt to reshape haptics in any way.
- After implantation the lens position must be Reversed-S.
- The long-term effects of intraocular lens implantation have not been determined. Therefore, physicians should continue to monitor patients postoperatively on a regular basis.
- Zaraccom intraocular lenses are posterior chamber lenses. The safety and effectiveness of a posterior chamber lens, if placed in the anterior chamber, has not been established.
- It is recommended that OVD be removed from the eye at the close of surgery with emphasis on the space between the posterior capsule and lens. This may be accomplished by gently depressing the IOL optic posteriorly with the irrigation/aspiration (I/A) tip while using standard I/A techniques to remove the OVD from the eye. This should force any trapped OVD anteriorly where it can be easily aspirated.
- if the instructions for use are not followed and/or used by persons other than a trained ophthalmic surgeon, "Abnormal Use" will occur, and the following hazardous situations may be encountered. Although this situation has no effect on the patient, it causes the intraocular lens not to be used in the operation.

  Abnormal Use Cases;
  - ✓ The intraocular lens gets stuck in the injector system,
  - ✓ Haptic rupture, breakage,
  - ✓ Scratches, cracks on the optical surface,
  - ✓ Uncontrolled protrusion of the intraocular lens from the injector.

SUGGESTED A-CONSTANT

The suggested A-constant indicated on the outer label is presented as a guideline and is a starting point for implant power calculations. It is recommended that you develop your own constant appropriate for you based on clinical experience with the particular lens models, surgical techniques, measuring equipment, and postoperative results.

If additional information on lens power calculation is needed, please contact with the manufacturer. The contact data are given at manufacturer details.

CALCULATION OF LENS POWER

Preoperative calculation of required lens power for these posterior chamber intraocular lenses should be determined by the surgeon's experience, preference, and intended lens placement. Lens power calculation methods are described in the following references:

Hoffer, K.J. The Hoffer Q Formula: A Comparison of Theoretic and Regression Formulas. J. Cataract Refract. Surg. 19:700-712, 1993.

Holladay, J.T., et al. A Three-part system for Refining Intraocular Lens Power Calculations. J. Cataract Refract. Surg. 14:17-24, 1988.

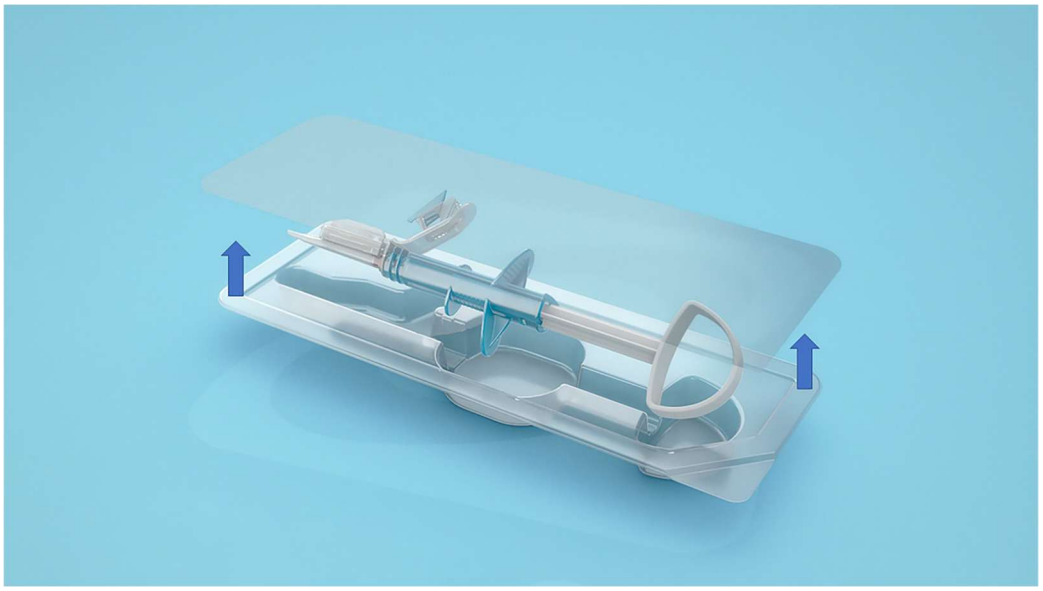
Holladay, J.T., et al. Standardizing Constants for Ultrasonic Biometry, Keratometry, and IOL Power Calculations. J. Cataract Refract. Surg. 23:1356-1370, 1997.

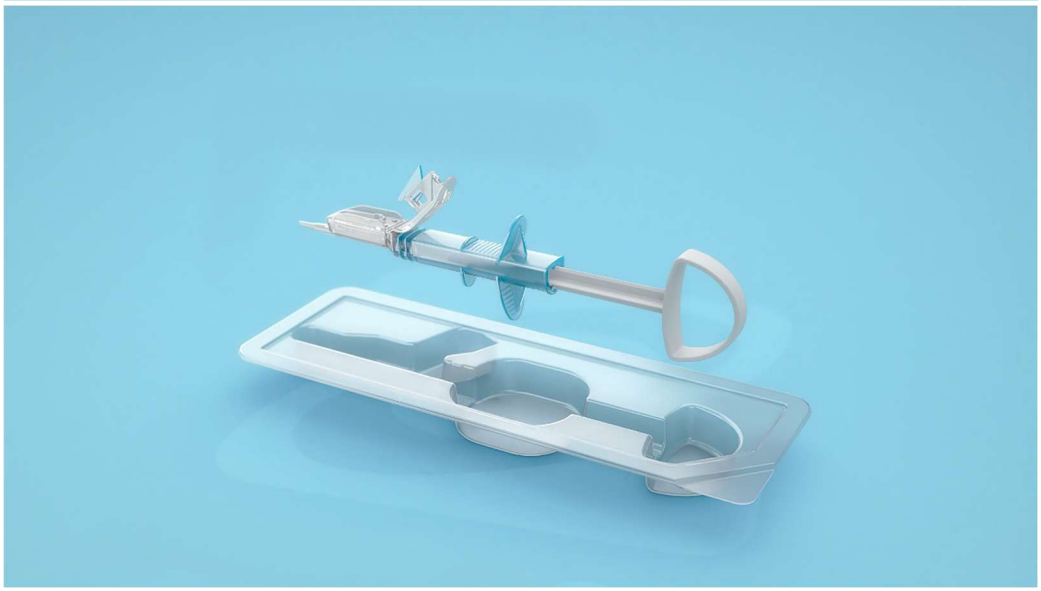
Retzlaff, J.A., Sanders, D.R., and Kraff, M. Lens Implant Power Calculation, 3rd ed., Slack, Inc., Thorofare, N.J., 1990.
HaigisW: The Haigis Formula, In: Intraocular lens power calculatios. H.John Sammas (eds)Slack Incorporated, Thorofare NJ, USA, pp 39-57, 2004

INSTRUCTIONS FOR USE

The injector system with preloaded lens is used to fold and implant Zaraccom aspheric IOLs in the capsular bag. The appropriate surgical technique is the responsibility of the surgeon. He or she must assess the suitability of the given procedure based on his or her education and experience.
Follow the steps as described below to ensure safe handling.

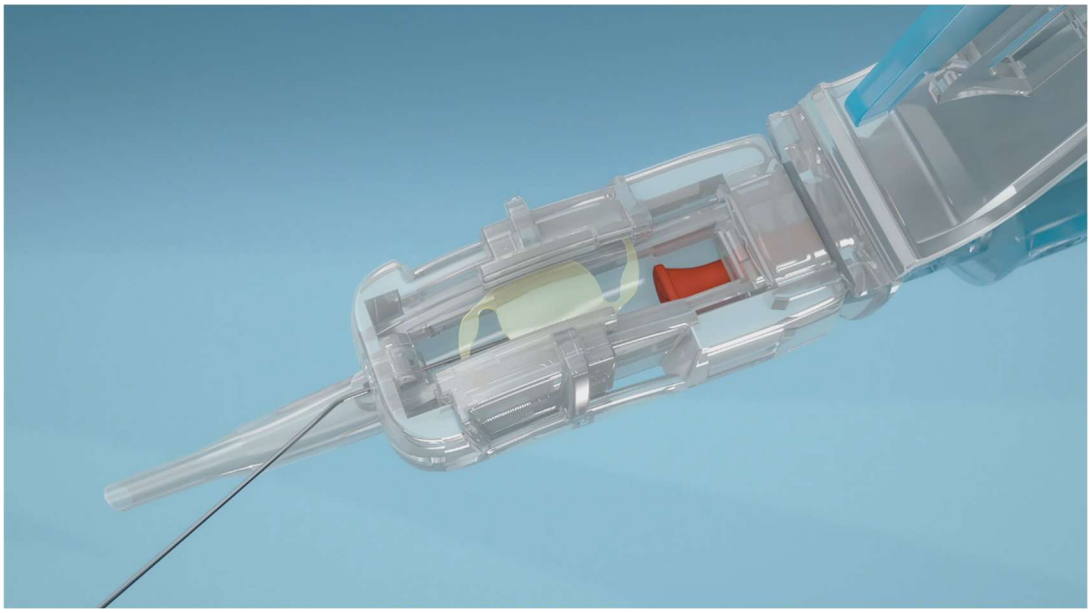
1. Prior to implanting, check the lens package for proper lens model, dioptric power, and expiration date.
2. Open blister containing sterile injector and the lens and place it in the sterile field.

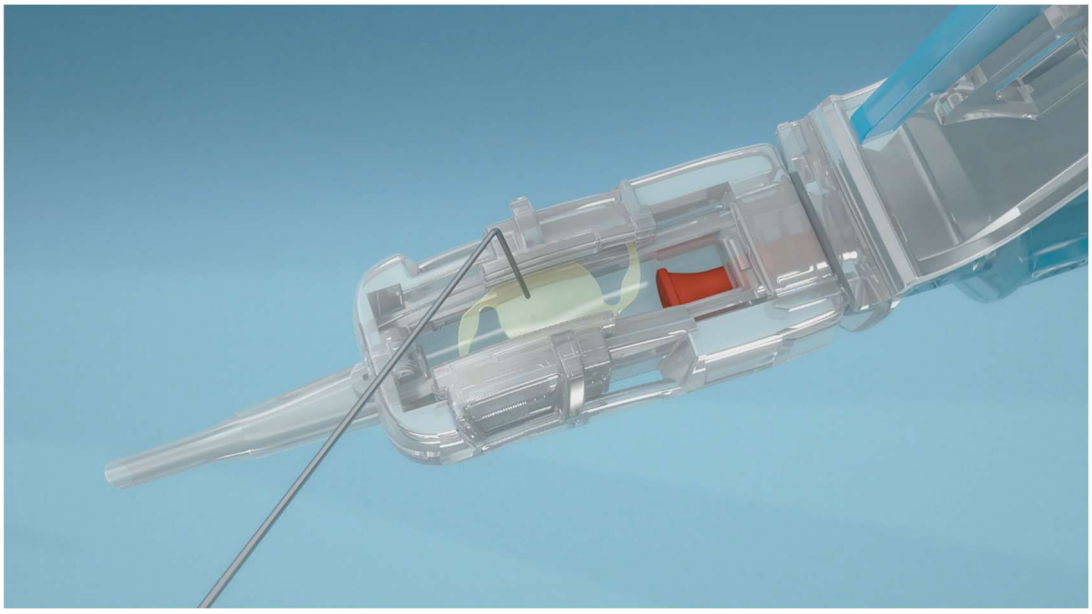




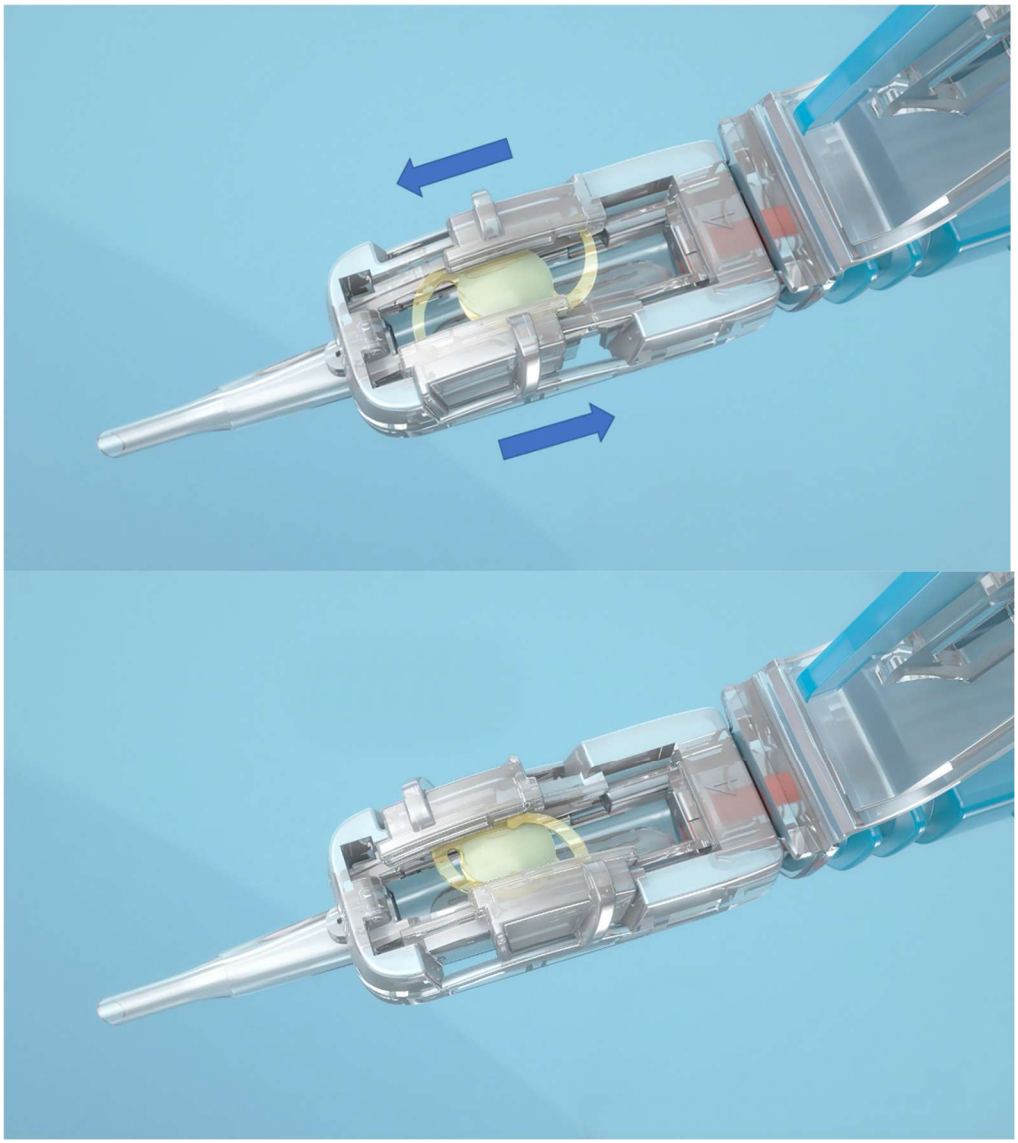
3. The lens is preloaded on the lens holder.

4. Hold injector around its midsection without exerting any pressure on the plunger. Rinse the injector nozzle with BSS. Next, fill injector nozzle with viscoelastic material either from above or through the nozzle tip, ensuring complete lubrication of inner nozzle surface. Lubricate both sides of the folding element with viscoelastic.

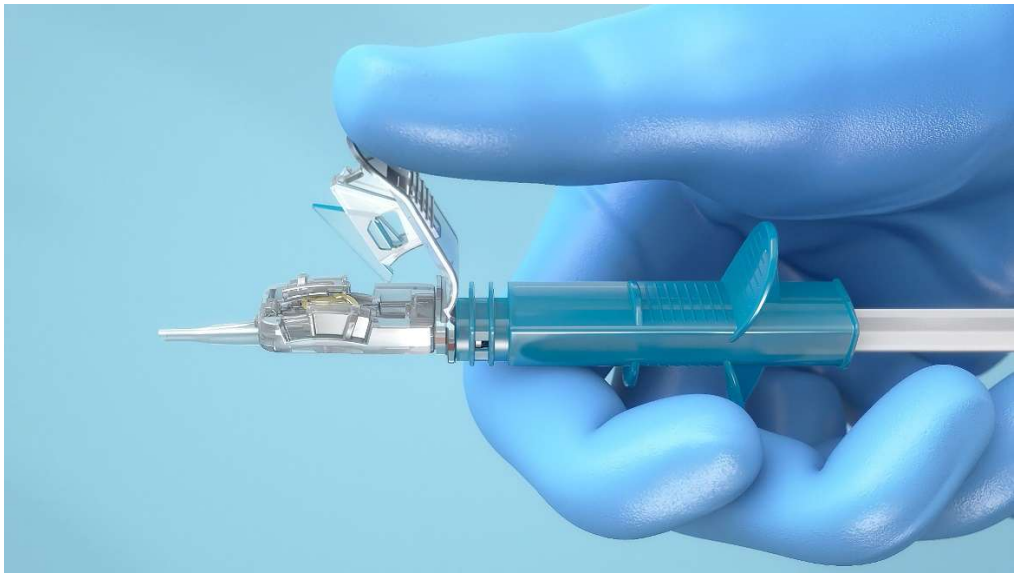




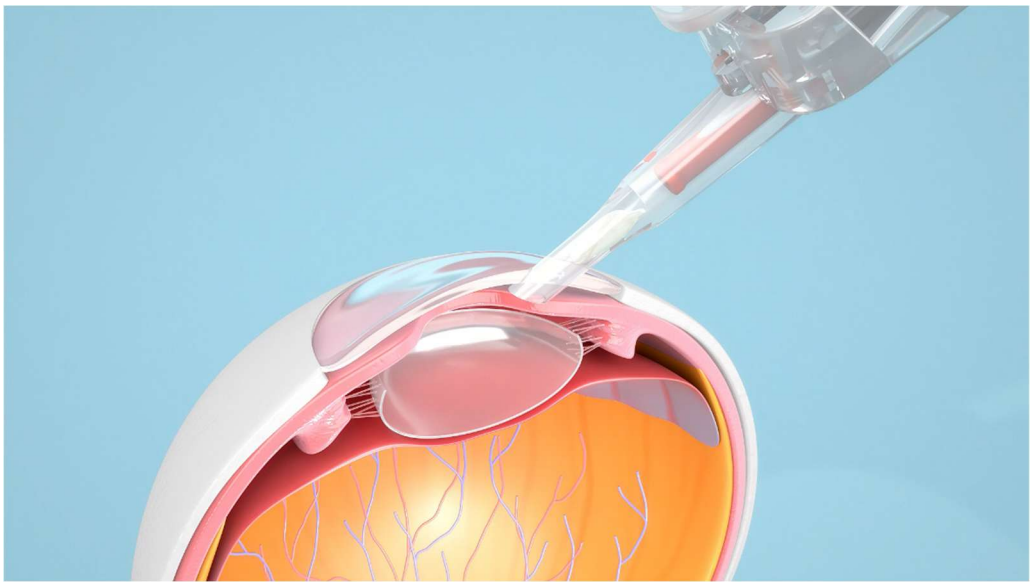
5. To load the lens from the lens holder in the injector, move the sliders to fold the haptics in the proper position to the end in the direction of the arrow. Check that the haptics have been folded correctly. Caution: Do not continue implantation until haptics are correctly folded onto the lens.



6. Gently push folding element into lens holder until a second ‘CLICK’ is heard. This signals that IOL injector system is securely ‘loaded’ and ready for injection.



7. Once loaded, the IOL should be injected immediately, as the viscoelastic may lose lubricity if allowed to stand too long while exposed to air.
8. Gently advance the plunger in a slow, even, and controlled manner, while ensuring the IOL haptics are correctly folded onto the IOL optic. If haptics are caught between plunger and injector nozzle, slacken pressure on plunger until IOL retraction is observed.
Caution: Do not continue implantation until haptics are correctly folded onto the IOL.



9. To proceed inject IOL by guiding injector tip through the incision. Stop pressing plunger when IOL exits injector. Do not let the injector soft tip exit the nozzle. Withdraw injector from eye.
10. Thoroughly remove viscoelastic material from eye and IOL with standard irrigation and aspiration techniques.
11. Disposal: After use, the injector system must be disposed in accordance with your clinical guidance for disposal of single use surgical instruments.
12. The lenses are carefully checked and inspected by manufacturer to assure a high-quality product. The lenses are to be studied carefully under surgical operation microscope before implantation. If a defect or deformation is noted or suspected, the lens should be returned to the manufacturer.
13. Implantation has to be performed by a trained ophthalmic surgeon to adult patients with aphakia.
14. Zaraccom posterior chamber lenses are designed for implantation, in the capsular bag by injector method through a 2,2 mm incision.

PATIENT IMPLANT CARD

The Patient Lens Implant Card included in the package is to be completed and given to the patient, together with instructions to keep the card as a permanent record to be shown to any eye care practitioner that the patient consults in the future.

To fill out the patient implant card:

1. To adhere it on the implant card, remove the product label from the box and adhere it to the place indicated on the implant card.
2. Fill out the following information on the implant card:

Date of surgery, Eye implanted [mark left (L) or right (R)], Patient name, Surgeon name, and Hospital or health institution name and address.

A copy of the patient information brochure is available at www.anadolutip.com.tr. Print a copy of the patient information brochure. Place a sticker one of the same labels to the patient information brochure before giving it to the patient.
In the EU, it is a requirement that the patient be given a completed implant card along with the patient information brochure.

MAGNETIC RESONANCE COMPATIBILITY

Zaraccom foldable hydrophobic IOL is magnetic resonance (MR) Safe. The IOL consists of acrylate/methacrylate copolymer material, which is a non-conducting, non-metallic, non-magnetic material that poses no known hazards in all magnetic resonance imaging environments.

LIFETIME OF THE IOL

Based upon material characterization of the Zaraccom IOL material, the IOL is expected to be stable indefinitely over the lifetime of the patient.

PACKAGING AND EXPIRATION DATE

Zaraccom lenses are supplied in dry, in a sterile blister package terminally sterilized with ethylene oxide, and must be opened only under aseptic conditions. The packaging sterility is guaranteed until expiry date except in case of damaging or opening of the package. The use-by date is clearly indicated on the outer box label of the carton. Any intraocular lens held after the use-by date should be returned to Anadolu Tıp Teknolojileri A.Ş.

DISPOSAL

Discarded IOLs and Cartridge Injector System / Preloaded Systems (used or unused (if opened from sterile packaging)) are classified as a potential source of infection or microbial hazard and should be disposed of as medical (clinical) waste according to regulatory practices.

LIABILITY

The manufacturer's liability covers the design and production of these intraocular lenses; it shall be incurred in no way in case of accidents resulting of the use of these lenses.

SERIOUS INCIDENT REPORTING

Any serious incident that may reasonably be regarded as device related should be reported to;

Anadolu Tıp Teknolojileri A.Ş.
By Phone: +90 346 2181418
By Email: mail@anadolutip.com.tr
Website: http://www.anadolutip.com.tr

Each IOL is identified by a serial number which provides traceability, and this information should be given to Anadolu Tıp Teknolojileri A.Ş.
NOTE: In Europe, these serious incidents must also be reported to the competent authority for medical devices of the appropriate State.

CLINICAL BENEFITS of ZARACCOM IOLs

Clinical evidence from published peer-reviewed clinical literature, clinical experience, and clinical investigations establishes an acceptable safety and performance profile for Zaraccom foldable hydrophobic IOL. The Zaraccom IOL was designed for visual correction of aphakia in adult patients following cataract surgery and has the following potential benefit:

ZARACCOM FOLDABLE HYDROPHOBIC ACRYLIC POSTERIOR CHAMBER LENS CLINICAL STUDIES

Two clinical studies have been performed on Zaraccom Foldable Posterior Chamber Lenses. These are summarized below.

1. EVALUATION OF EFFICACY AND SAFETY OF ZARACCOM F260 INTRAOCULAR LENSES IN CATARACT TREATMENT: A National, Multicenter, Prospective Clinical Device Study Including Historical Control Group

Totally, 363 patients (females 49.03%, males 50.97%) were analyzed and the mean age was 67.11±10.19.

Efficacy Results: Compared to pre-operative values, visual acuity was significantly improved at post-operative 1st-2nd days, 7th-14th days, 30th-60th days, 120th-180th days and 330th-420th days ($p<0.001$ for each). In the comparison of VA rates between the patients with and without pre-operative ocular pathology, statistically significant difference was observed between groups on the post-operative 1st-2nd days ($p<0.001$), 7th-14th days ($p<0.001$) and 30th-60th days ($p=0.002$). Total numbers of patients who had insufficient visual acuity were 95 on postoperative 1st-2nd days, 35 on post-operative 7th-14th days, 15 on post-operative 30th-60th days, 19 on post-operative 120th-180th days and 9 on post-operative 330th-420th days. There was an improvement in visual acuity with time.

Table2. Best Corrected Visual Acuity in the Best Case Patient Population at a Minimum of One Year Postoperatively, Zaraccom F260

	1st-2nd days		7th-14th days		30th-60th days		120th-180th days		330th-420th days	
Age (year)	n/N	%	n/N	%	n/N	%	n/N	%	n/N	%
<=50	19/22	86.4	19/19	100.0	20/20	100.0	19/19	100.0	20/21	95.2
51-60	53/65	81.5	52/55	94.5	41/43	95.3	58/59	98.3	61/61	100.0
61-70	89/132	67.4	107/115	93.0	103/109	94.5	106/115	92.2	126/130	96.9
71-80	77/119	64.7	89/104	85.6	81/85	95.3	94/102	92.2	114/119	95.8
81+	9/21	42.9	15/20	75.0	13/17	76.5	14/16	87.5	14/15	93.3
Total	247/359	68.8	282/313	90.1	258/274	94.2	291/311	93.6	335/346	96.8

Safety Results:

Safety was evaluated according to cumulative and persistent adverse events rates specified in ISO 11979-7:2006. Cumulative adverse events are those which occurred at any time during the subjects' postoperative follow-up. Totally, 1 secondary surgery interventions (0.28%) was present throughout the study. Persistent adverse events are those which are present at postoperative 330th-420th days. No persistent adverse events were observed in the study.

Table3. Cumulative Adverse Events at a Minimum of One Year Postoperatively Zaraccom F260

	N (=363)	%
Cumulative secondary surgery intervention	1	0.28*
Occurrence time of adverse event		
Post-operative 1st-2nd days (N=363)	1	0.28
Age groups		
61-70	1	0.28
Centers		
Center No 2	1	0.28
Total	363	100.00

*Difference is not statistically significant when it is compared with FDA grid (0.8%) ($X^2=1.12$, $p=0.291$).

2. EVALUATION OF EFFICACY AND SAFETY OF ZARACCOM UF60125 INTRAOCULAR LENSES IN CATARACT TREATMENT: A National, Single-center, Prospective Clinical Device Study Including Historical Control Group

Totally, 98 patients (females 40.8%, males 59.2%) were analyzed and the mean age was 64.5±12.9 years.

Efficacy Results:
The number of patients who had sufficient visual acuity were 67 (70.5%) on post-operative 1st-2nd days, 88 (91.7%) on post-operative 7th-14th days, 90 (93.8%) on post-operative 30th-60th days, 90 (94.7) on post-operative 120th-180th days and 90 (95.8%) on post-operative 330th- 420th days. There was an improvement in visual acuity with time.

Table4. Best Corrected Visual Acuity in the Best Case Patient Population at a Minimum of One Year Postoperatively, Zaraccom UF60125

	Before operation		1^{st}-2^{nd} days		7^{th}-14^{th} days		30^{th}-60^{th} days		120^{th}-180^{th} days		330^{th}-420^{th} days	
Age	n/N	(%)	n/N	(%)	n/N	(%)	n/N	(%)	n/N	(%)	n/N	(%)
<=50	5/13	38.5	11/12	91.7	13/13	100.0	13/13	100.0	13/13	100.0	13/13	100.0
51-60	4/19	21.1	15/20	75.0	16/20	80.0	17/20	85.0	18/20	90.0	19/20	95.0
61-70	10/24	41.7	19/25	76.0	25/25	100.0	25/25	100.0	25/25	100.0	25/25	100.0
71-80	8/29	27.6	18/30	60.0	27/30	90.0	28/30	93.3	28/30	93.3	28/30	93.3
81+	1/7	14.6	4/8	50.0	7/8	87.5	7/8	87.5	6/7	85.7	7/8	87.5
Total	28/92	30.4	67/95	70.5	88/96	91.7	90/96	93.8	90/95	94.7	92/96	95.8

Safety Results:
Safety was evaluated according to the cumulative and persistent adverse events rates specified in ISO 11979-7:2006. No cumulative or persistent adverse events were observed in the study.

General Safety Data:
The reported studies and publications found provide evidence that medical devices with a high similarity to the Zaraccom IOL are safe for use. It shall be noted that complications may occur due to the surgical intervention as a matter of fact or if the device not being used according to the IFU. For safety data, only inflammatory findings have been reported in intraocular lenses as a post-operative pathology. As an adverse event, only one patient had secondary surgery interventions.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE (SSCP)

Additional information about 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.

SYMBOLS USED ON LABELING

SYMBOL	EXPLANATION	SYMBOL	EXPLANATION
REF	*Catalogue number*	SN	*Serial Number*
UDI	Unique device identifier		*Date of manufacture*
	Single *sterile* barrier system	MD	*Medical Device*
STERILE EO	*Sterilized using ethylene oxide*		*Use by date*
35 °C (95°F) 5°C (41°F)	*Temperature limit: lower temperature limit is 5⁰C (41⁰F) and upper temperature limit is 35⁰C (95⁰F)*	CE 0476 **European Conformity Mark Notified Bodies: KIWA (0476)**	*The product conforms to European Medical Device Regulation 2017/745 and meets applicable health, safety and environmental requirements. If the mark is accompanied by a number, conformity is verified by the indicated notified body*
2 STERILIZE	*Do not resterilize*		Keep away from sunlight
2	*Do not re-use*		*Do not use if package is damaged and consult instructions for use*
	Manufacturer		Consult *instructions for use* or consult electronic *instructions for use*
#	*Model number*		Keep dry

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

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