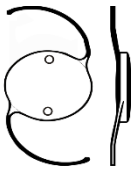
INSTRUCTIONS FOR USE

Truelens™ TRUE SQUARE EDGE PC IOL Posterior Chamber IOL



DEVICE DESCRIPTION:

Truelens are optical devices designed for the replacement of human crystalline lens in the visual correction of aphakia in patients 18 years of age or older. To allow the surgeon's flexibility in meeting individual patient requirements, several distinct types of lenses are available from -10.00 D to +40 diopter in 0.05 increments.
The IOL comprises of two parts, the central clear optic (which acts as visual zone) and the peripheral Haptic (which helps in lens anchorage.)

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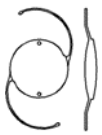
The optical part's edge has 150 microns deep square edge on the posterior side. The haptics have a steep vault with 0.60 mm Vault depth from haptics to optics center plane. This feature makes sure the posterior side of the optics fits tight in the capsular bag.

Optic Material: Polymethyl Methacrylate (PMMA) Clear Material
Optic Design: Monofocal, Spherical
Configuration: Biconvex optic
Diopter range: -10.00 to +40.0 diopters in 0.5 increments
Refractive Index: 1.49
Estimated A-Constant: 119.0
AC Depth:5.00 mm

PRODUCT TECHNICAL SPECIFICATION:

Model	Optic Size (mm)	Overall Length (mm)	Position Hole	Optic Design	Placement	Image	Haptic Design
TSE 5503	5.50	12.50	0	Single Piece Biconvex, Continuous 360° Posterior Square edge	Posterior Chamber		Mod C
TSE 6023	6.00	12.50	2		Posterior Chamber		Cap C

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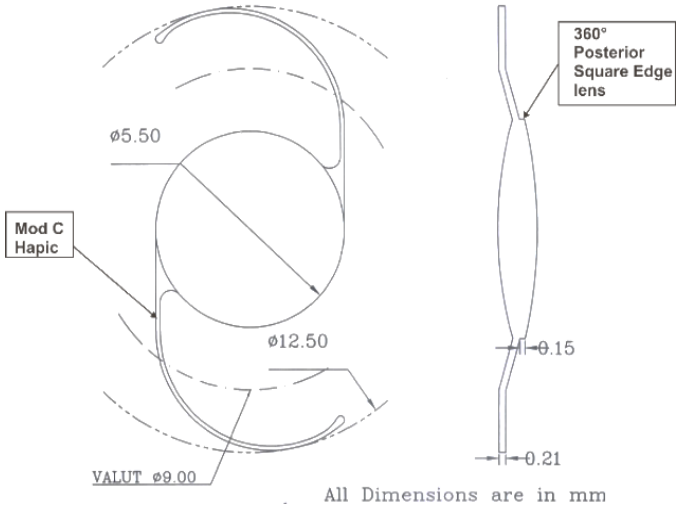
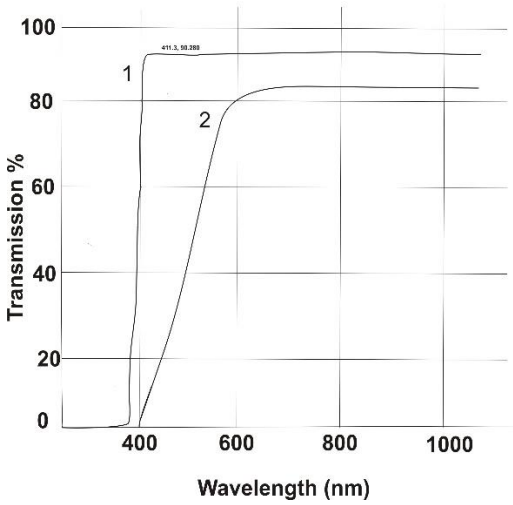


Square Edge Lens

The spectral transmittance curve below represents the transmittance values of the IOL. Transmission (%)



1.Spectral transmission (UV) of Intraocular Lens of 20 D
2. Spectral Transmission (UV) of a blind due to a cataract of 53 years. (According to Boettner & Wolter Transmission of ocular media.1962, INVEST OPTHAL 1,776,783)

(Figure 1: Transmittance graph of EXCELENS PMMA IOL)

INDICATIONS

"Excelens", TRUELENS is a clear PMMA one-piece Posterior Chamber Intraocular Lens. The intraocular lens is designed to be used for visual correction of aphakia for primary implantation for the visual correction of aphakia with adult patients where a cataractous lens has been removed by extra capsular extraction methods. It is intended for implanting in the Posterior chamber of the eye.

INTENDED USER:

Ophthalmic surgeons only.

INTENDED PURPOSE:

The Lens is intended to provide vision correction after the eyes natural lens is removed because of cataract surgery.

PATIENT TARGET GROUP:

Aphakic adult patients of age 18 years and above.

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MODE OF ACTION:

The PMMA TRUELENS 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.
It functions as a refractive element to help in focusing the light rays which are coming through the cornea on to the retina.

CALCULATION OF LENS POWER:

The power of the lens to be implanted should be determined preoperatively.
Prerequisites of successful visual outcomes of cataract surgery include accurate biometry. Pre-surgery calculation of required lens power should be determined using expertise by the surgeon as per the preference. An estimated theoretical A-Constant value is mentioned on the IOL packaging outer label. These reference A-Constants anticipate the use of other parameters corneal curvature and axial length values from respective biometry equipment, required for power calculation and a spectacle distance vision at 6 meters or 20 feet. IOL power calculation methods are often included with biometry equipment, and they are also described in the references mentioned below. It is recommended to personalize the lens A constants to compensate differences in instrumentation, surgical techniques, and IOL power calculation formulas that may exist between clinical practice.

- Retzlaff, J.A., Sanders D.R., and Kraff, M.C., "Development of the SRK/T intraocular lens implant power calculation formula," Journal of Cataract and Refractive Surgery, Vol. pp. 222-240, 1990; ERRATA, Vol. 16 pp. 528, 1990.
- Hoffer KJ. The Hoffer Q formula: a comparison of theoretic and regression formulas. J. Cataract Refract Sur. 1993;19(6):700-12.
- Holladay JT. et al Standardizing constants for ultrasonic biometry, keratometry, and intraocular lens power calculations. J. Cataract Refract Surg. 1997;23(9):1356-70. Sanders, D.R., Retzlaff, J., and Kraff, M.C., "Comparison of the SRKII formula and other second-generation formulas," Journal of Cataract and Refractive Surgery Vol. 14, pp. 136- 141, 1988.

CONTRAINDICATIONS:

- Patients with the following conditions are not suitable candidates for IOL implantation. If doing so, it may pose unreasonable risk to the patient's eyesight.
- Patients with eyes having foreshortened anterior segments, e.g., micro-ophthalmic or certain forms of chronic angle-closure glaucoma.
- For anterior chamber implantation, previous history of, or predisposition to retinal detachment.
- Patients in whom the IOL may interfere with the ability to observe, diagnose, or treat posterior segment disease.
- Recurrent anterior or posterior segment inflammation of unknown etiology.
- Abnormality of the iris which would preclude adequate fixation of the lens, such as aniridia, hemi-iridectomy or severe atrophy.

WARNINGS, UNDESIRABLE SIDE EFFECTS AND RESIDUAL RISK:

- The complications listed below may occur following implantation of any IOL and may require treatment, or in severe cases can lead to secondary surgery for which the surgeon should carefully evaluate the risk/benefit ratio.
- Possible complications linked to surgery for crystalline lens removal and IOL implantation include, but are not limited to, those listed below. The risks of accidents and side effects are practically same as found during the extraction of cataract in particular: lens dislocation, non-pigment precipitates, corneal endothelial damage, high intraocular pressure, infection (endophthalmitis),corneal edema, pupillary membranes, flat anterior chamber, iris prolapse, hypopyon, and secondary glaucoma, Temporary Collapse of the anterior Chamber, Retinal detachment, Pupillary block, Iridocyclitis, Vitritis, Temporary Fistula, Cystoid macular edema, Formation of a posterior membrane, Hyphema, Vascular occlusion , Dystrophy of corneal endothelium, Striated Keratitis, Hernia of vitreous in anterior chamber, Subluxation or luxation of lens, Secondary reopacification, Evisceration or enucleation, Presence of Intra-ocular debris, Ophthalmitis, Malposition of the lens, Ablation of the lens.
- The effectiveness of UV-inhibiting intraocular lenses in reducing the incidence of retinal disorders has not been established.

INSTRUCTIONS FOR USE

- Special consideration should be given to the dimensions of lenses at the extreme ends of the power range in relation to the anatomical clearances in the patient's eye. The potential impact of factors such as optic central thickness, optic edge thickness and overall lens size on a patient's long-term clinical outcome must be carefully weighed against the potential benefit associated with the implantation of an intraocular lens. This is particularly true for anterior chamber lenses. The patient's clinical progress should be carefully monitored.
- Patient's regular follow-up is especially important after the implantation of the anterior chamber lens which includes the monitoring of the changes in the intraocular pressure and corneal endothelial cell count.

PRECAUTIONS:

- Do not store the lens in direct sunlight or at temperature greater than 40° C. keep from freezing.
- Do not use if sterile pouch is opened or damaged.
- Only skilled surgeons with experience in either viewing and / or assisting numerous surgical implantations and successfully completed at least one course on IOL implantation should attempt implantation of these lenses.
- Pouch should be opened only under sterile conditions.
- Do not soak or rinse lens in solutions other than sterile balanced salt solution or sterile normal saline solution equivalent of such solution.
- Do not attempt to re-sterilize this lens.
- Do not autoclave this lens.
- Handle the lens carefully. Looking forceps or needle holders should never be used to pick up lenses.
- Do not reshape the supporting structures (haptics).
- The patient must be advised that the doctor or the medical centre should be informed of any side effects not referred in this information.

Note: Because the lens and the packaging materials are plastic, the lens may pick up an electrostatic charge upon opening the package. The lens should be carefully examined to ensure that particles have not been attracted to it.

Implantation of intraocular lenses should not be performed in patients under the age of 18.

DIRECTIONS FOR USE:

Preparatory Steps:

- Prior to implantation examine the lens of power, type, proper configuration, and optical surfaces.
- During insertion handle lenses by haptic portion only.
- Carton box contains extra labels. These are for convenience in maintaining and reporting records of implantable lenses during clinical investigation. One the labels could be affixed in patients case sheet, for future reference.
- "Rinse the lenses in sterile B.S. Solution before implantation to minimize the static discharge which enhance the microbial contamination".

Implanting Steps:

- In a sterile environment, peel apart to open the pouch and remove the lens case.
- Unscrew the lens case with care and grasp the lens optics using smooth edged forceps and lift.
- Soak or rinse lens in sterile balanced salt solution or sterile normal saline solution.
- The lens, due to some static charge produced while opening the lens case, may stick to the cap in rare instances.
- Ensure that the lens is in good condition for optic and haptic surfaces for adherence of any particles.
- Do not attempt to re sterilize this lens.
- Do not autoclave this lens.
- Handle the lens carefully. Locking forceps or needle holders should never be used to pick up lenses.

CLINICAL BENEFITS:

- The clinical benefit of the implantation of an IOL for cataract patients is the prevention of blindness.
- EXCELENS AC Lens provides functional far vision, improves patients' quality of life.

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HOW SUPPLIED:

Each carton box contains one IOL, an implant card, (instructions for completion of implant card is given below) and product traceability labels. Excelens Intraocular lenses are supplied in a lens case contained within a heat-sealed Tyvek peel pouch and terminally sterilized using Ethylene Oxide (EO). The contents of the pouch are sterile unless the package is opened or damaged. The outer box should be opened in sterile condition only.

IMPLANT CARD:

The implant card supplied with this device is to be completed by the healthcare provider. A product traceability label also supplied with this device must be affixed to the implant card after completion of the surgery. Additional labels can be used for the patient file or clinical follow-up. Completed implant cards must be provided to the patient post-procedure. Patients should be instructed to keep the card as a permanent record of their implant. The patient should also be instructed to show the card to any eye practitioner he or she may see in the future.

WARNINGS:

- The effectiveness of UV - absorbing intraocular lenses in reducing the incidence of retinal disorders has not been established.
- The safety of the use of the Neodymium-YAG laser and IOLs with UV absorbing materials has not been established. The physician is urged to use extreme caution in such cases where a patient with UV absorbing IOLs is treated with a Neodymium – YAG laser.
- The compression force exerted on the eye tissue by the lens is not established. The physician should have knowledge in the selection of the type of lens depending on the eye dimensions.
- Care should be taken to avoid breakage of haptic while inserting lens through the sclera tunnel of small incision.

REPORTING OF SERIOUS INCIDIENTS:

Users should report the serious incident with medical device information to the manufacturer and/or to the national competent authority depending on the national practice. Once corrective (or other) action is identified from the manufacturer, hospital administrators, medical practitioners, and other health- care professionals, and USER representatives responsible for the maintenance and the safety of MEDICAL DEVICEs, can take the necessary steps. Such steps should, where practicable, be taken in co-operation with the MANUFACTURER. For the purposes of Medical Devices Vigilance System in member states are represented by appointed National Competent Authorities, their vigilance contact points being listed on the European Commission web site: http://ec.europa.eu/growth/sectors/medicaldevices/contacts/index_en.html.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE:

Summary of Safety and Clinical Performance (SSCP) of this device will be available on the EUDAMED websitehttps://ec.europa.eu/tools/eudamed after notified body acceptance of SSCP.

CAUTION:

GOVERNMENT LAWS RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

DISPOSAL:

Discarded IOLs (used or unused) are classified as medical (clinical) waste that harbours a potential infection or microbial hazard and must be disposed of accordingly.

STORAGE CONDITIONS:

Store between 0°C to 40°C temperature.

EXPIRATION DATE:

- The expiration date on the lens package is the sterility expiration date.
- Do not use the IOL after the expiration date.

LIMITATION OF WARRANTY AND LIABILITY:

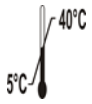
EXCEL OPTICS (P) LIMITED accepts no liability for any injury suffered to patients as a result of:

- Any implantation method or technique used by a physician to implant the lens.
- Any prescription, and use of the lens for any individual patient or patient's conditions.

Excel Optics (P) Limited, makes no expressed or implied warranties in connection with the sale of the IOL.

INSTRUCTIONS FOR USE

Symbols and their Explanations

EC REP	Authorized Representative in the European community	IOL	Intraocular Lenses
STERILE EO	Sterilized using Ethylene Oxide		Do not re-sterilize
	Storage Condition between 5°C to 40°C		Keep away from sunlight
	Manufacturer		Consult Instructions for Use
LOT	Sterile Batch No		Keep Dry
UDI	Unique device identifier	MD	Medical Device
SN	Serial Number		Single sterile barrier system with protective packaging inside
#	Model Number		Use by Date
	Do not Use If package is Damaged		Date of Manufacturer
	Country of Manufacture	PC	Posterior Chamber
UV	Ultraviolet		Do Not re-use
	Caution		

EC REP

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