ARTIFLEX® PHAKIC IOL

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en | REF **40114SW** | | **INSTRUCTIONS FOR USE**

This IFU is available electronically on our website. Please visit: www.ophtecimplants.info

DESCRIPTION
The ARTIFLEX® phakic intraocular lens (IOL) is a unique three-piece lens consisting of a flexible optical part made of ultraviolet absorbing silicone and rigid haptics made of ultraviolet light absorbing polymethylmethacrylate (PMMA). The lens is designed for implantation into the phakic human eye for the correction of a refractive error. The lens is fixated to the relatively immobile anterior midperiphery of the iris stroma by two iridoplastic bridges with enclavation mechanisms ("claws").

SPECIFICATIONS

Construction	Three - Piece Design	
Material optic	Polysiloxane elastomer with bound UV absorber	
Material haptics	Ultraviolet light absorbing PMMA	
Material specification	Polysiloxane elastomer	≈ 99% Silicone Elastomer, <0.5% UV blocker
	PMMA	≈ 99% Polymethyl methacrylate (PMMA), <0.5% UV blocker
	Adhesive	Silicone sealant
Optic diameter	6.0 mm	
Body configuration	Convex – concave	
Overall diameter	8.5 mm	
Available powers	-2.0D to -14.5D (0.5D increments)	
Performance indicators		
UV cut-off wavelength (<10%)	360 nm	
Light transmittance	> 90% in the visible spectrum	
Refractive index	1.43	

INTENDED PURPOSE
Indications
The ARTIFLEX® Phakic IOL is indicated for the correction of myopia, in patients aged 18 and older, when there are no compromising ocular pathology(ies).

Intended user
The ARTIFLEX® Phakic IOLs are intended to be used by a healthcare professional.

Use environment
The implantation of the ARTIFLEX® Phakic IOLs will be carried out in a controlled environment, or more specific a hospital setting.

Contraindications
Patients with any of the following conditions may not be suitable candidates for receiving an ARTIFLEX® Phakic IOL.
Pre-existing pathology or physiology which may be aggravated by the implant or where the implant may interfere with the possibility of examining or treating disease:
- Abnormal cornea (e.g. keratoconus, opaque cornea, corneal scars, post corneal transplant, corneal dystrophy);
- Abnormal iris (e.g. convex, bulging or volcano shaped iris);
- Abnormal pupil (e.g. nonreactive, fixed, ectopic pupil);
- Acute or chronic inflammation;
- Aged under 18;
- Cataract of any grade;
- Choroidal hemorrhage;
- Chronic or recurrent uveitis or family history of the same condition;
- Corneas with high rates of polymegathism (a coefficient of variation > 0.40) and pleomorphism (the presence of ≤ 50% hexagonal cells);
- Corticosteroid responder;
- Crystalline lens rise of 600 µm or more;
- Diabetes or diabetic retinopathy;
- Glaucoma or family history of glaucoma;
- High preoperative intraocular pressure (> 21 mm Hg);
- Patient not meeting age specific minimum preoperative endothelial cell density as follows:

< 25 years of age	2950 cells/mm²
26 - 30 years of age	2650 cells/mm²
31 - 35 years of age	2400 cells/mm²
36 - 45 years of age	2200 cells/mm²
> 45 years of age	2000 cells/mm²

- Pregnant or nursing;
- Preoperative anterior chamber depth measurement of below 3.0 mm from corneal endothelium to the anterior pole of the crystalline lens. A preoperative anterior chamber depth of below 3.0 mm will result in a critical distance between IOL and endothelium of below 1.5 mm as simulated with anterior segment imaging;
- Preoperative ocular or systemic condition or medication use that would be expected to present undue risk to the subject or that can predispose for future complications. E.g. the systemic use of alpha-1a adrenergic receptor antagonists was suggested to increase the occurrence of intraoperative floppy iris syndrome, alter iris morphology – or more specifically reduce iris thickness at the site of potential IOL enclavation – and increase postoperative endothelial cell loss;
- Pupil in scotopic light conditions greater than 7.0 mm;
- Retinal detachments or family history of retinal detachments;
- Significant amount of astigmatism (greater than 2 diopters);
- Unstable refraction (≥0.5D of variability in refraction over the last 12 months);
- White-to-white smaller than the overall diameter of the IOL plus 2.0 mm.

LIFETIME
Under normal conditions and medical circumstances, the expected lifetime of an ARTIFLEX® Phakic IOL is at least 20 years.

CLINICAL BENEFITS
The intended clinical benefit of the ARTIFLEX® Phakic IOL is the improvement of the uncorrected visual acuity resulting in a reduced spectacle need for distance vision. The outcome parameters are the measurements of visual acuity and spectacle dependency.

COMPLICATIONS
As with any surgical procedure, there is risk involved. Potential complications accompanying implant surgery may include but are not limited to the following:
- Ametropia (spectacle dependency)
- Aniseikonia (spectacle dependency)
- Astigmatism (surgically induced)
- Cataract (surgically induced)
- Corneal edema and decompensation
- Cystoid macular edema
- Dysphotopsia (e.g. halos/glares)
- Endophthalmitis (intraocular infection)
- Endothelial cell loss (severe)
- Flat anterior chamber
- Glaucoma
- High intraocular pressure (uncontrolled)
- Hyphema
- Hypopyon
- IOL decentration
- IOL precipitates
- IOL (sub)luxation
- Iris atrophy
- Iris erosion
- Iris perforation
- Iris prolapse
- Myopic shift
- Ocular infection (e.g. cornea, conjunctiva)
- Ocular pain
- Pupil ovalization
- Pupillary block
- Pupillary membrane
- Retinal detachment
- Synechiae
- Toxic Anterior Segment Syndrome (TASS)
- Urrets Zavalia syndrome

Some of these complications may necessitate a secondary surgical intervention (e.g. IOL exchange, removal or repositioning) or specific treatment (e.g. corticosteroids).

PRECAUTIONS
- A high level of surgical skill and training specific to iris-fixated IOLs is required for ARTIFLEX® lens implantation. Training courses for iris-fixated IOL implantation are provided by OPHTEC BV.
- This device is restricted to the use by a physician with training specific to iris-fixated IOLs and may only be used in compliance with appropriate medical guidelines.
- An iridotomy or iridectomy outside the IOL periphery should be performed to reduce risk of high ocular pressure as a result of pupillary block.
- In addition to standard postoperative examinations, postoperative follow-up after six months and annual examinations are required, including but not limited to intraocular pressure, endothelial cell density monitoring and anterior chamber measurements. Device explantation should be considered when abnormal endothelial cell patterns are observed or when endothelial cell count is less than 1500 cells mm².
- Disposal of waste products of the device must be in accordance with Good Hospital Practices.
- See sections "PATIENT INFORMATION for the physician" and "PATIENT INFORMATION for the patient" for other relevant precautions.

WARNINGS
- For single patient use only. Do not reuse, reprocess or resterilize, this may compromise the structural integrity of the device and/or create a risk of contamination. Malfunction and cross-contamination may lead to injury or illness of the patient.
- Do not resterilize.
- Do not reuse.
- Do not use after the expiration date.
- Do not use if the integrity of the product or the packaging has been compromised.
- Do not store at temperatures >40°C or 104 °F.
- Do not soak the IOL in fluids other than a sterile balanced salt solution.
- Prior to implantation, verify that the correct product and lens power has been selected for the concerning eye.
- The physician must ensure traceability of the IOL and provide the patient with a patient implant card.

The residual risks are addressed by warnings, precautions and contraindications.

CALCULATION OF LENS POWER
The dioptric power of the phakic IOL has to be calculated for each eye. It is important that accurate preoperative biometry measurements are taken. Preoperatively, the physician can provide OPHTEC BV with the subjective manifest refraction, the anterior chamber depth and the keratometry values. Based on the "van der Heijde" formula and the data provided by the physician a recommendation for the lens power of the lens will be provided.

Contact OPHTEC BV for more information on lens power calculation.

PATIENT INFORMATION for the physician
All patients receiving this lens should be given an extensive preoperative ocular examination. In addition, the physician should provide thorough counselling to the patient on the potential risks as well as benefits of refractive surgery with the ARTIFLEX® Phakic IOL. In order to assess the safety of the lens over time, patients should be examined 6 months after surgery and subsequently once a year. The follow-up examination should include monitoring of intraocular pressure, endothelial cell counts and anterior chamber measurements. Follow-up frequency should be increased to once every six months in case the decrease in cell count exceeds the physiological norm or when the anterior chamber becomes shallower. Patients should be instructed not to rub the eye after the implantation and to avoid physical impact or direct pressure to the eye, and to avoid activities that increase the risk of ocular trauma (e.g. certain ball sports, martial arts) or to wear safety glasses during such activities.
In case of malfunction of the lens or changes in its performance, the patient should be instructed to contact the physician.

PATIENT INFORMATION for the patient
Information for the patient can be found on our website: www.ophtecimplants.info.

OPERATING INSTRUCTIONS
Prior to implantation, all packaging should be carefully examined to verify that the contents have not been damaged, the correct lens power has been chosen and that the expiration date is respected. Using a sterile technique, open the blister pack and deliver the lens tray with the lens to the sterile prep tray. Open the lens tray and examine the IOL for damage or debris. The IOL may be rinsed with sterile balanced salt solution or coated with a viscoelastic prior to implantation to facilitate easy passing through the main incision.

SURGICAL PROCEDURE
A full description of the surgical procedures for implantation, re-enclavation and explantation of the ARTIFLEX® Phakic IOLs can be found on the company website: www.ophtec.com.

RECOMMENDATION FOR USE WITH OTHER DEVICES
The use of specific ARTIFLEX® instruments developed by OPHTEC BV is recommended:
ARTIFLEX® Insertion spatula
ARTIFLEX® Reusable Implantation Forceps Left
ARTIFLEX® Reusable Implantation Forceps Right
ARTIFLEX® Reusable Manipulator
ARTISAN®/ARTIFLEX® Disposable Enclavation Needle
ARTISAN®/ARTIFLEX® VacuFix™ Disposable Vacuum Enclavation System

Viscoelastic Substances
Only a high viscosity sodium hyaluronate (1.0-1.4%) viscoelastics such as ArtiVisc® or ArtiVisc Plus® should be used.

HOW SUPPLIED
Each lens is supplied sterile in a protective tray sealed in a blister pack and packaged in a box. Attached to the box and blister pack are labels containing the lens model, serial number, expiration date, lens power, a description of the lens and the UDI code.

PATIENT IMPLANT CARD
A patient implant card is provided with each lens implant. The physician or physician's staff should fill in the appropriate information on each card and instruct the patient to carry the card at all times in case emergency medical treatment is necessary. Please check the symbol explanation table below to complete the patient implant card correctly.

RETURN LENS POLICY
A request for return or exchange should always include a specification of the model of the intraocular lens, dioptric power, serial number, customer reference and reason for return. Please contact OPHTEC BV for more information regarding the policy for the return/exchange of intraocular lenses.

SERIOUS INCIDENTS
Any Serious Incident that has occurred in relation to one of OPHTECs IOLs must be reported immediately to OPHTEC BV at tel. (+31) 505251944 or by e-mail info@ophtec.com and to the competent authority of the Member State in which the user and/or patient is established.

CLINICAL INVESTIGATION DATA
A summary of the results of the clinical investigation can be found on our website: www.ophtec.com

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE
A summary of safety and clinical performance (SSCP) is available in the European database on medical devices (Eudamed) at https://www.ec.europa.eu/tools/eudamed. The SSCP is linked to the Basic UDI-DI number 8717819Artiflex401/TV .

DISCLAIMER OF LIABILITY
OPHTEC BV shall not be liable for any injury or damage suffered by a patient as a result of:
- The surgical technique or implantation method used by a physician to implant the IOL;
- Improper patient selection;
- Improper product selection.

OPHTEC BV makes no expressed or implied warranties in connection with the resale of its intraocular lenses or the fitness for use other than the intended purpose, as defined by the manufacturer, and/or the specified operational conditions.

PRODUCT OF THE NETHERLANDS

CE 0344 STERILE EO

Symbol	Explanation	Symbol	Explanation
REF	Catalogue number		Date of manufacture
STERILE EO	Sterilized by ethylene oxide	MD	Medical Device
	Do not resterilize	UDI	Unique Device Identifier
	Do not reuse		Single Sterile Barrier System
	Use by		Patient Identification
	See Instructions for Use	31	Date of Implantation
SN	Serial number	OS	Left Eye
x°C (x°F)	Upper limit of temperature	OD	Right Eye
	Do not use if package is damaged		Healthcare Centre/Doctor
	Manufacturer		Information website for patients

More information can be obtained by contacting:
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