VETERINARY FOLDABLE INTRAOCULAR LENS

Rev01

VETERINARY INTRAOCULAR LENS

INSTRUCTIONS FOR USE

WARNING!

This device is to be implanted only by an experienced veterinary ophthalmic surgeon trained in the implantation technique for posterior chamber intraocular lens.

1. DESCRIPTION

IOVET posterior chamber foldable intraocular lens (IOL) is an optical implant for the replacement of the animal lens in the correction of aphakia post-specific cataract removal surgical procedure. It is a one-piece posterior chamber lens made of foldable hydrophilic acrylic that has a UV radiation filter (wavelength less than 360 nm - transmittance less than 10%).

Due to the elastic characteristics of the material and structural resources employed, the lens can be injected through small incisions. After surgical implantation in the animal's eye, the lens unfolds smoothly, regaining its original optical performance and shape.

2. PRESENTATION

The IOVET Foldable Intraocular Lens is individually presented sterile, sterilized by moist heat (autoclave), in a glass bottle with 0.9% saline solution, with polyethylene cap and Teflon Seal, sealed in a sterilization packages.

Each final package contains 1 (one) unity of product (IOL), 1 (one) unit of instructions for use, 6 (six) unity of implant traceability labels, 1 (one) unity of product identification card for the patient.

In case where Disposable Injection Instrument is supplied with the IOL, see the Instructions for using this product, also included in the final lens packaging.

This product is for single use and the reprocessing is prohibited. Re-sterilization using physical methods (dry heat or steam) or chemical methods (ethylene oxide) will compromised the physical condition and/or the characteristics of the device causing damage to the patient.

3. MECANISM OF ACTION

The IOVET Foldable Intraocular Lens was designed to be positioned within the capsular bag in the posterior chamber, adding a refractive power in the aphakic eye to replace the animal lens after its extraction, which normally occurs to correct the opacification of this lens due to cataract. IOVET has aspherical biconvex optics, with structural features that ensure maximum optical performance with the smallest central thickness. The mechanical platform of this lens was designed to better adapt to the different sizes of capsular bag evaluated by the veterinarian based on the patient's biometrics.

4. INDICATIONS

The IOVET Foldable Intraocular Lens is an implantable veterinary medical device indicated to replace the animal natural lens for the correction of aphakia after a specific surgical procedure for cataract removal, which can be by extracapsular extraction or phacoemulsification technique. The IOVET intraocular lens implant is intended for use in the capsular bag.

5. CONTRAINDICATIONS

The IOVET Foldable Intraocular Lens is intended for adequate performance when ametropy is the goal. Patients presenting any of the following conditions may not be suitable candidates for intraocular lens implantation in general, because these can aggravate an existing condition, interfere with the diagnosis or treatment of an existing condition, or present an unreasonable risk to the patient's vision. Careful preoperative evaluation and clinical assessment by the surgeon is needed to determine the benefit/risk ratio before implanting the IOL in a patient with one or more of the following conditions:

Before surgery:

1. Irregular optical aberration;
2. Retinal conditions or predisposition to retinal conditions in which future treatment may be compromised by IOL implantation;
3. Severe corneal dystrophy;
4. Extremely shallow anterior chamber not due to swollen cataract;
5. Anterior or posterior segment inflammation of unknown etiology or any illness which may cause ocular inflammation;
6. Predisposition to or prior history of retinal detachment;
7. Aniridia;
8. Neovascularization of the iris;
9. Glaucoma (uncontrolled or controlled by medication);
10. Microphthalmos, macrophthalmos;
11. Optical atrophy;
12. Descemet's membrane endothelial keratoplasty (DSEK) or Descemet's picking automated endothelial keratoplasty (DSAEK) or Vitrectomy surgery.

During surgery:

1. Need for surgical or mechanical manipulation to increase pupil size;
2. Significant vitreous loss;
3. Significant anterior chamber bleeding;
4. Uncontrollable positive intraocular pressure;
5.In the presence of the following conditions the surgeon should decide whether stability of the intraocular lens will be compromised:

· Zonular damage;
· Rupture/tear of the capsulorrhexis;
· Decentered capsulorhexis;
· Capsular rupture.

Note: ViZoo does not recommends the use of the device for situations that not indicated in this instructions, as this may impact the product's performance and/or generate possible adverse events. In these cases the use will be user's responsibility.

6. WARNINGS

General warnings for all posterior chamber intraocular lenses:

As with any surgical procedure, there are risks involved. Potential complications accompanying cataract or implant surgery are as follows, but are not limited to: injury to the corneal endothelium, infection (endophthalmitis), retinal detachment, anterior and/or posterior segment inflammation, vitritis, pupillary block, membrane cyclitic, iris prolapse, hypopyon, persistent or transient glaucoma, guttata cornea and/or mild fibrinoid reaction, accumulation of fibrin on the lens surface, TASS (Toxic Anterior Segment Syndrome), lens opacification, intraocular infection, severe corneal decompensation , advanced laucomatous disk damage, high intraocular pressure or ocular hypertension, macular edema, mild choroidal effusion, hyphema, phimosis of anterior capsule, vitreous hemorrhage, vitreous cord around incision, reactivation of uveitis, unwanted images, unwanted shadows), decentering or slight displacement or rotation of the intraocular lens. The adverse reactions described can cause secondary surgical interventions.

Use only sterile intraocular irrigation solutions to rinse and/or wet the lenses.

Handle the lens carefully to avoid damage to the lens surface or the fixing handles.

·Improper handling of the lens or remodeling of the handles can cause damage to the lens and the damaged product should not be implanted. The medical device must immediately disposed of in medical waste, according to the procedure established at the institution where the surgical procedure would be performed.

The injection of intravitreal gas, air in the posterior chamber or buffering with silicone oil can cause opacification of the intraocular lens.

Medicines that are not intended for ocular and intraocular use should not be administered to the patient, otherwise the lens may be damaged and the intended use of the product may not be achieved.

ViZoo does not recommend the use of the device for situations that are not indicated in the Instructions for Use, as this may impact the product's performance and/or generate possible adverse events. In these cases, the use will be the user's responsibility.

If there is a suspicion of quality deviation in the product, it should not be implanted and should be forwarded to ViZoo Customer Service (SAC) so that the product can be evaluated for its quality.

If complications or adverse events associated with the implantation of the IOVET intraocular lens are suspected, the ViZoo's SAC must be informed.

The safety and efficacy of intraocular lens implantation in patients with preexisting eye conditions (chronic drug miosis, glaucoma, amblyopia, diabetic retinopathy, previous corneal transplantation, previous retinal detachment and/or iritis, etc.) have not been confirmed. The veterinarian, when considering the lens implant in these patients, should explore the use of alternative methods of aphakia correction and consider lens implantation only if the alternatives are considered unsatisfactory for the patient's needs.

Patients with preoperative problems, such as diseases of the corneal endothelium, abnormal cornea, macular degeneration, retinal degeneration, glaucoma and chronic drug miosis may not achieve the same visual acuity as patients without these problems. The veterinary must determine the benefits of lens implantation when such conditions exist.

The viscoelastic of the eyeball must be completely aspirated at the end of the surgery, mainly from the space between the posterior capsule and the lens, in order not to compromise the patient's intraocular pressure. This procedure can be performed by carefully pushing the optical zone of the intraocular lens in the posterior direction with the I/A tip, using standard irrigation/aspiration techniques to remove the viscoelastic from the eye. Then, position the I/A tip behind the IOL optical zone to irrigate/aspirate any remaining viscoelastic that may have been retained behind the lens and then gently press the lens back into position.

The factors mentioned below may favor the occurrence of IOL opacification, such as: prolonged postoperative intraocular inflammation and/or prolonged uveitis, glaucoma, posterior capsule and need for vitrectomy, diabetics patients, gas or air injection, posterior vitrectomy via the plane or DMEK or DSAEK, complicated cataract surgery, patients with a medical history of hypertension, arthritis, kidney failure, hypercholesterolemia, hypothyroidism and not completely removing the viscoelastic after surgery.

The use of dyes such as Methylene Blue, Sodium Fluorescein, Indocyanine Green and Trypan Blue can stain the IOL, which can be clinically identified as IOL opacification, but it is adsorption of the eye.

Note: Failure to observe the warnings described above may compromise the results of the intended use of the product.

7. CARE FOR USE AND STORAGE

- The medical device must not be used after the expiry date stated on the packaging. The use of the expired product does not guarantee the maintenance of the product's sterility.
- Do not re-sterilize this intraocular lens by any method. The device is sterile until the bottle containing the lens is opened.
- Medical device for single use. Do not re-sterilize. Reprocessing prohibited. The re-sterilization of the product may not be effective and cause inflammatory reactions and contamination of the patient.
- The handling of these lenses must be done in compliance with aseptic techniques. The use of the product without observing how aseptic techniques can promote inflammatory reactions and/or contamination of the patient.
- The handling of this device requires the use of appropriate techniques and instruments in order to guarantee the integrity of the device and the performance of the sugical techniques. Any device damaged during its handling must not be implanted, and must be disposed of in the hospital waste according to the procedure established in the institution where the surgical procedure would be performed.
- Do not use if sterile package is opened or damaged. The damaged packaging can compromise the sterility of the product, causing risk of contamination in the patient. The device must be immediately disposed of in hospital waste, according to the procedure established in the institution where the surgical procedure would be performed.
- If for any reason the sterile package is opened and the device is not implanted, the device must not be used and must be immediately disposed of in hospital waste, according to the procedure established at the institution in where the surgical procedure would be performed.
- Check the information regarding the implant such as the model, diopter, configuration, and expiry data before opening the sterile package. Store the Intraocular Lens at room temperature. Product stored outside the recommended conditions can impact its stability, compromising its intended use.
- Do not spray cleaning solutions, disinfectants and/or insecticides in the storage and storage areas. Do not use substances with Terpene, Ketone, Borate, Phosphate Ester and Phenol for pest control of the product's storage and storage areas. These substances may be a factor in the cause of opacification. Implant identification tags provided must be affixed to the patient, hospital and/or surgeon records, in order to allow tracking of each implant to the end user, according to current national and international standards.
- The implantation of the device must be performed in a sterile room with all precautions associated with intraocular surgical procedures.
- Products containing alcohol, iodine and silicone derivatives must not come into contact with the lens, at the risk of damaging it and compromising its intended use.
- Temperature limit 18 to 25°C, stored at room temperature and in the humidity range of 30 to 70 RH %.

Note: Failure to comply with the care described above may compromise the results of the intended use of the product.

8. PATIENT PREPARATION

- Tutor should be instructed not to use any type of product on the patient, especially around the eyes, on the day of surgery.
- Tutor should be instructed on the importance of using all postoperative medication, according to the prescription.
- Tutor should be instructed to contact the veterinarian immediately if the animal presents pain, irritation, restlessness in the postoperative period.
- Tutor should be instructed about the post-surgical follow-up of the animal to be performed to evaluate the results achieved and surgical complications, the frequency of this follow-up must be defined by the surgeon.

Note: Failure to comply with the care described above may compromise the results of the intended use of the product.

9. ADVERSE REACTIONS

Some adverse reactions associated with intraocular lens implantation are: hypope, accumulation of cells in the lens, capsular opacification, fibrin accumulation on the surface of the lens, TASS (Toxic Anterior Segment Syndrome), lens opacification, intraocular infection, severe corneal decompensation , advanced laucomatous disk damage, high intraocular pressure or ocular hypertension, macular edema, mild choroidal effusion, hyphema, phimosis of anterior capsule, vitreous hemorrhage, vitreous cord around incision, reactivation of uveitis, decentralization or slight lens displacement or rotation of the intraocular lens. The adverse reactions described can cause secondary surgical interventions.

Secondary surgical interventions include, but are not limited to: repositining and reimplantation of the lens, aspiration of the vitreous or iridectomy by pupillary block, repairs and repairs by incision due to detachment of the retina.

Note: This device must be implanted exclusively by a veterinary ophthalmologist surgeon wiht experience and training in the posterior chamber intraocular lens implantation technique and the management of related adverse reactions.

10. CARE FOR USE AND HANDLING OF THE INTRAOCULAR LENS

- Examine the label of the sealed outer packaging to identify the model, diopter, configuration and expiration date of the sterilization.
- Inspect the sterile envelope carefully for tears, cuts, perfurations or other signs that it has been damaged or opened. Do not implant the IOL if sterility has been compromised.
- To remove the lens, open the packaging in a sterile environment. Carefully open the container to expose the lens.
- To minimize the occurrence of marks on the lens due to fold, all instruments should be carefully cleaned. Any tweezers used to handle the lenses must have rounded edges and regular surfaces.
- When removing the lens from the container, do not press the optical area with the forceps. The IOL should only be handled by the handles.
- Rinse the lens using only sterile balanced saline. Before being implanted, lenses must be carefully examined to ensure that particles have not adhered during handling to avoid inflammatory reactions and contamination of the patient.
- There are several different techniques and instruments for implanting intraocular lens. The surgeon must establish a technique that seems preferable for each patient and execute it according to the prescribed modalities.
- To use the injection device, proceed with the assembly of the cartridge according to the instructions for use of the injection device to be used.
- When an intraocular lens injection device is used, the cartridge must be observed to be intact, without the presence of foreign bodies or particles that may damage the intraocular lens. If damage to cartridge is observed or presence of foreign bodies or particles that cannot be removed by instilling irrigation solution, the injector must not be used under the risk of damage to the intraocular lens.

11. EXPIRATION

IOVET Foldable Intraocular Lens is sterilized in a steam autoclave, under controlled conditions and a validated process. Sterility is guaranteed, provided that the sterile envelope is not opened or damaged. The expiration date is clearly indicated on the outside of the package and sterile envelope. The lens should not be used after this date.

12. RULES FOR RETURNS AND EXCHANGES

Contact the ViZoo customer-service department for information about the exchange policy.

13. EXEMPTION FROM LIABILITY

ViZoo Oftalmologia LTDA shall not be liable any injury or damage suffered by the patient resulting from any method or technique used by the surgeon to implant this intracular lens nor for the prescription, selection and use of this intraocular lens in a particular patient. The surgeon is responsible for the selection or performance of any implantation method or technique, as well for prescribing and using this lens in any particular patient.

14. SYMBOLOGY

Símbolo / Symbol	Título do Símbolo / Symbol Tittle
	Fabricante / Manufacturer
	Data de fabricação / Date of manufacture
SN	Número de série / Serial number
REF	Número de referência / Catalogue number
LOT	Lote / Batch code
STERILE	Esterelizado usando vapor / Sterilized using steam
	Não reutilizar / Do not reuse
	Não reesterilizar / Do not resterilize | Proibido reprocessar / Reprocess is forbidden
	Leia as instruções de uso / Read the instructions for use
	Data de validade / Use-by date
	Limite de temperatura / Temperature limit
	Cuidado / Caution
#	Número de modelo / Model Number
$\varnothing_B$	Diâmetro do corpo (diâmetro óptico) / Body diameter (optical diameter)
$\varnothing_T$	Diâmetro total / Overall diameter
D	Dioptria / Diopter

ViZoo Oftalmologia Veterinária Ltda.
Av. Barão Homem de Melo, 4386,
SL 802/803 | Estoril - Belo Horizonte
MG | 30494-080 - Brasil
www.vizoovet.com.br
Phone: +55 31 99147-3420
CNPJ: 43.723.078/0001-47

Mediphacos Indústrias Médicas S/A
Av. Deputado Cristovam Chiarádia, 777 | Buritis
Belo Horizonte – MG | CEP: 30.575-815 – Brasil
www.mediphacos.com
Phone: +55 31 2102-2211
CNPJ: 21.998.885/0001-30