

VETERINARY INTRAOCULAR LENS FOR ANTERIOR CHAMBER

Rev01
IOVET AC

INSTRUCTIONS FOR USE

WARNING!

This device should only be implanted by a veterinary surgeon with experience and training in the technique of implanting intraocular lenses.

1. DESCRIPTION

The Veterinary Intraocular Lens (IOL) for Anterior Chamber IOVET AC is an optical implant for replacing the animal lens in the correction of aphakia after a specific surgical procedure for cataract removal or lens dislocation. The IOL is composed of a biocompatible polymethylmethacrylate (PMMA) polymer with a high refractive index and UV radiation filter.

2. PRESENTATION

The Veterinary IOL for Anterior Chamber IOVET AC is individually presented in a sterile way, in a neutral plastic cradle, sealed in a surgical grade sterilization envelope. The envelope is packed in a cardboard cartridge. Each final package contains 1 (one) unit of the product, 1 (one) unit of instructions for use, 6 (six) units of implant traceability labels and 1 (one) unit of product identification card for the patient.

This is a single-use product and should not be reused or resterilized.

3. MECHANISM OF ACTION

The Veterinary IOL for Anterior Chamber IOVET AC was developed to be positioned in the anterior chamber, supported by the trabecular meshwork, replacing the natural lens of the eye. This position allows the lens to function as a refractive medium in correcting aphakia. The Veterinary IOL for Anterior Chamber IOVET AC has aspherical biconvex optics, with structural resources that guarantee maximum optical performance with the smallest central thickness. Its mechanical platform was designed for better adaptation to different anterior chamber sizes and the indication must be made after evaluation by the veterinarian.

4. INDICATIONS

The IOVET AC Veterinary IOL for Anterior Chamber is an implantable veterinary medical device indicated for replacing the animal's crystalline lens for the optical correction of aphakia after a specific cataract removal procedure or lens luxation, which can be by extracapsular extraction or phacoemulsification. The IOVET AC Veterinary Anterior Chamber IOL implantation is intended to be performed in the anterior chamber.

5. CONTRAINDICATIONS FOR USE

The IOVET AC Veterinary Anterior Chamber IOL is intended for adequate performance when targeting emmetropia. Patients with any of the following conditions may not be suitable candidates for IOL implantation in general, as they may exacerbate an existing

condition, may interfere with the diagnosis or treatment of that condition, or may pose an unreasonable risk to the patient's vision. Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to determine the benefit/risk balance before implanting the lens 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 whose future treatment may be compromised by lens implantation;
3. Severe corneal dystrophy;
4. Extremely shallow anterior chamber, other than due to an intumescent cataract;
5. Recurrent anterior or posterior segment inflammation of unknown etiology or any disease that may produce an inflammatory reaction in the eye;
6. Predisposition or previous history of retinal detachment;
7. Aniridia;
8. Atrophy of the iris
9. Neovascularization of the iris;
10. Glaucoma (uncontrolled or controlled with medication);
11. Microphthalmos, macrophthalmos;
12. Optic atrophy;
13. Descemet's membrane endothelial keratoplasty (DESK) or Descemet's automated stripping endothelial keratoplasty (DSAEK) or vitrectomy surgery;
14. Irregular or abnormal anatomy of the anterior chamber, including the iris, angle, pupil, cornea or other surrounding structures;
15. Inadequate support for the intraocular lens.

During surgery:

1. Need for surgical or mechanical manipulation to enlarge the pupil.
2. Vitreous loss (significant).
3. Anterior chamber bleeding (significant).
4. Uncontrollable increased intraocular pressure.

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

6. WARNINGS

- Handle the IOL carefully to avoid damage to the lens surface or attachment loops.
- Improper handling of the IOL or reshaping the handles can cause damage to the lens and the damaged product must not be implanted. The medical device must be immediately disposed of in the medical waste, in accordance with the procedure established in the institution where the surgical procedure will be performed.
- Injection of intravitreal gas, posterior chamber air, or silicone oil tamponade can cause IOL opacification.
- Medicines that are not intended for ocular and intraocular use must not be administered to the patient's eye, otherwise the IOL may be damaged and the intended use of the product may not be achieved.
- ViZoo does not recommend using 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 responsibility of the veterinarian.

- If there is suspicion of quality deviation in the product, it should not be implanted and should be forwarded to ViZoo's 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 AC Veterinary Anterior Chamber IOL are suspected, ViZoo SAC must be informed.
- The safety and efficacy of IOL implantation in patients with preexisting ocular conditions (chronic drug-induced miosis, glaucoma, amblyopia, diabetic retinopathy, previous corneal transplantation, previous retinal detachment and/or iritis, retinal degeneration, in the corneal endothelium, abnormal cornea, etc.) and these patients may not achieve the same visual acuity as patients without these problems. The veterinarian, when considering IOL implantation in these patients, should explore the use of alternative methods of correcting aphakia and consider IOL implantation only if the alternatives are deemed unsatisfactory for the patient's needs.
- It is recommended to aspirate all the viscoelastic solution from the eyeball at the end of the surgery, in order not to compromise the patient's intraocular pressure.
- The factors mentioned below may favor the occurrence of IOL opacification, such as: Prolonged postoperative intraocular inflammation and/or prolonged uveitis, glaucoma, rupture of the posterior capsule and need for vitrectomy, diabetic patients, injection of gas or air, posterior vitrectomy via flat or DMEK or DSAEK, complicated IOL implantation surgery, patients with a clinical history of hypertension, , 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.

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

7. PRECAUTIONS FOR USE AND STORAGE

The Veterinary IOL For Anterior Chamber IOVET AC is sterilized by ethylene oxide under special conditions of temperature, pressure, humidity, exposure time and aeration. The IOL must not be resterilized by any method. The device is sterile until the sterile envelope containing the IOL is opened.

- The medical device must not be used after the expiry date indicated on the packaging. The use of the expired product does not guarantee the maintenance of the sterility of the product.
- Medical device for single use. Do not resterilize. Reprocessing prohibited. Product resterilization may not be effective and may cause inflammatory reactions and patient contamination.
- The handling of these lenses must be done with observance of aseptic techniques. The use of the product without observing aseptic techniques can promote inflammatory reactions and/or contamination of the patient.
- The manipulation 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 surgical technique. Any device damaged during manipulation should not be implanted and should be disposed of in 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. Damaged packaging can compromise the sterility of the product, causing a risk of contamination for the patient. The device must be immediately discarded 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, it must not be used and must be immediately discarded in hospital waste, according to the procedure established in the institution where the surgical procedure would be performed.
- Check implant related information such as model, diopter, total diameter and expiry date before opening the sterile package. Store the IOL at room temperature. Product stored outside the recommended conditions may impact its stability, compromising its intended use.
- Do not spray cleaning solutions, disinfectants and/or insecticides in storage and storage areas. Do not use substances with Terpene, Ketone, Borate, Phosphate Ester and Phenol for fumigation in the product's stock and storage areas. These substances may be a factor in causing clouding. Implant identification labels provided must be affixed to the patient's, hospital and/or surgeon's records, in order to allow the tracking of each implant to the end user, in accordance with current national and international standards.
- Device implantation 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 limits 18 to 25°C, storage at room temperature and humidity range 30 to 70 RH %.

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

8. PATIENT PREPARATION

- The tutor must be instructed not to use any type of product on the patient, especially around the eyes, on the day of surgery.
- The tutor must be instructed on the importance of using all postoperative medication, according to the prescription.
- The tutor must be instructed to contact the veterinarian immediately if the animal presents pain, irritation, restlessness in the postoperative period.
- The tutor must be instructed about the post-surgical follow-up of the animal to be carried out 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 precautions described above may compromise the results of the intended use of the product.

9. ADVERSE REACTIONS

As with any surgical procedure, there are risks involved. Potential complications accompanying cataract or implant surgery include, but are not limited to: corneal endothelial damage; infection (endophthalmitis); retinal detachment; anterior and/or posterior segment inflammation; vitreitis; corneal edema; pupillary block; fibrovascular membrane; iris prolapse, persistent or transient hypopyon and

glaucoma, mild fibrinoid reaction, accumulation of fibrin on lens surfaces, TASS (Toxic Anterior Segment Syndrome), lens opacification, severe corneal decompensation, elevated intraocular pressure or ocular hypertension, choroidal effusion mild, hyphema, vitreous hemorrhage, vitreous cord around the incision, reactivation of uveitis, glare or other visual disturbances under certain light conditions, decentration or slight displacement or rotation of the IOL. The adverse reactions described may lead to secondary surgical interventions, such as repositioning and reimplantation of the IOL, repairs to the incision, repairs due to retinal detachment, among others.

Note: This device should only be implanted by a surgeon experienced and trained in the technique of anterior chamber IOL implantation and the management of related adverse reactions.

10. CARE FOR USE AND HANDLING OF THE IOL

1. Examine the unopened outer packaging label for identification of model, diopter, total diameter and expiration date.
2. Inspect the sterile envelope carefully for tears, cuts, punctures, or other signs that it has been damaged or opened. Do not implant the IOL if sterility has been compromised.
3. To remove the lens, open the envelope and remove the case in a sterile environment. Carefully open the plastic case to expose the lens.
4. When removing the lens from the case, do not press the optical area with tweezers. The IOL must be handled by the handles only. Any tweezers used to handle lenses should have rounded edges and smooth surfaces.
5. Rinse lens using sterile intraocular irrigation solution. Prior to being implanted, lenses must be carefully examined to ensure that particles have not adhered during handling to avoid inflammatory reactions and patient contamination.

11. VALIDITY

The Veterinary IOL For Anterior Chamber IOVET AC is sterilized by ethylene oxide under controlled conditions and validated process. Sterility is guaranteed as long as the sterile envelope is not opened or damaged. The expiry date is clearly indicated on the outside of the package and on the sterile envelope. After this date, the lens must not be used.

















12. RETURN AND EXCHANGE RULES

Contact ViZoo customer service for information about the exchange policy.

13. DISCLAIMER OF LIABILITY

ViZoo Oftalmologia Veterinária Ltda. is not responsible for any injury or damage suffered by the patient resulting from any method or technique used by the medicine to implant this intraocular lens, nor for the prescription, selection and use of this in a particular patient. Discomfort is responsible for the selection or performance of any implantation method or technique, as well as the prescription and use of that lens in any particular patient.

14. SYMBOLOGY

Symbol	Symbol Title
	Manufacturer
	Date of manufacture
	Serial number
	Catalogue number
	Batch code
	Sterilized using ethylene oxide
	Do not reuse
	Do not resterilize /Reprocess is forbidden
	Read the instructions for use
	Use-by date
	Temperature limit
	Caution
	Model Number
	Body diameter (optical diameter)
	Overall diameter
	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 - Brasil | CEP: 30.575-815
www.mediphacos.com
Phone: +55 31 2102-2211
CNPJ: 21.998.885/0001-30
Responsible Technician: Aline L. Freitas CRFMG: 23364