

DIOPTRIX ACRYLIC INTRAOCULAR LENS

Sterile - Do not re-sterilize! One lens per box.

Description

The DIOPTRIX intraocular lens (IOL DIOP) is a medical device used to replace the natural crystalline lens of animals. IOLs are created by the machining of clinical grade hydrophilic acrylic (Co-Polyhema) with UV filter and 25% hydration. DIOPTRIX intraocular lenses are designed to be inserted into the posterior chamber.

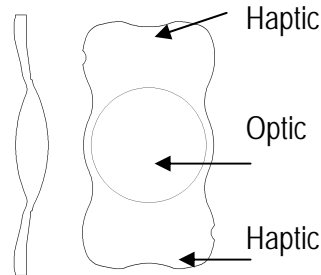
Resolution greater than 60%
MTF >0.43 (Modulation Transfer Function)

Use as guide only:

DIOP 12: 3.30 lbs/1.5 kg to 20 lbs/9.0 kg

DIOP 13: 22. lbs/10.kg to 55. lbs/25kg :

DIOP 14: Above 55. lbs/25kg :



Presentation

Each DIOPTRIX intraocular lens is individually packaged in a sterile and hydrated double blister. The first blister contains the second one, which in turn contains the folding support, the IOL and the saline solution. In addition to the blister, the protective packaging contains the present leaflet, the patient's card and the traceability stickers.

Indications

Aphakia following surgical removal of the crystalline lens in the animal's eye.

Instructions for removal from primary packaging

The box should be stored at room temperature (22°C/71°F) for a min. of 3 hours prior to implanting. Storing <16°C/60°F, may cause short-term opalescence due to the heat shock that occurs with implantation (the phenomenon is reversible within 30 minutes).

1. Open the first blister by pulling the membrane seal and free the second blister.
2. Open the second blister, at the time of the surgical procedure, above the sterile field, by pulling the aluminium membrane seal.

The folding support is designed for handling with forceps. (the clearance at the rear of the support is used to pick up the implant flat for use with an injector).

Instructions for use

The DIOPTRIX hydrophilic acrylic intraocular lens has been designed to be implanted in a saccular position for animals (to the rear of the iris). The DIOPTRIX IOL, thanks to its dioptric power, is able to perform crystalline lens functions. Various surgical techniques can be used for implanting the intraocular lenses. The surgeon is responsible for selecting the most suitable technique.

The IOL's hydrated presentation requires careful handling using appropriate instruments.

The use of DIOPTRIX IOLs is indicated for correcting aphakia, following ablation of the natural crystalline lens. Incision size shall be determined by the use of forceps or injector.

Contraindications

1. Absolute contraindications:

Predominantly chronic cases with potentially unfavourable results according to experience.

- Chronic or recurring uveitis
- Severe corneal dystrophy
- Uncontrolled glaucoma
- Acute eye disease or infection

2. Relative contraindications

Clinical cases which may deteriorate due to IOL implantation and cases with an increased risk caused by implantation.

The individual evaluation of each single case is left to the surgeon.

3. Surgical contraindications

- Hyphema
- Excessive vitreous loss
- Zonular damage
- Posterior capsular rupture
- Presence of, or predisposition to, retinal detachment

Side effects/interactions

No side effects or drug interaction have been reported.

Warnings

- Prior to use, check the sterility expiration date. The manufacturer cannot be held responsible for any product use after the expiration date. Lens is out of date the first day of the month indicated on the box.
- Check packaging integrity prior to use. Sterility is valid only if the packaging shows no sign of damage.
- In the event of packaging damage, or after opening, the product must not be re-sterilized by any method.
- Use only physiological saline.
- Avoid the use of silicone oil.
- In the event of serious adverse effects:
 - 1) Contact the manufacturer immediately.
 - 2) Return the IOL, along with all data required for traceability, under the conditions stated during contact.

Disclaimer

DIOPTRIX cannot be held responsible for any lesions or damage caused to the animal following:

- the surgical technique or implantation method used by the surgeon.
- the prescription or choice of intraocular lens.

Guarantee

CRISTALENS guarantees its intraocular lenses against any form of faulty manufacture.

HANDLING AND STORAGE:

Sterile-do not re-sterilize. Store at room temperature.

Protect from light and humidity. Do not freeze.

Handle with care-do not crush packaging.

It is strongly recommended the DIOPTRIX IOL be inserted ONLY with the AQUAJECT Injector System.

Manufactured in France by



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