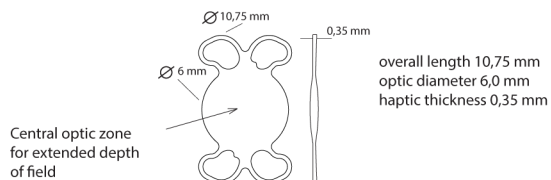


# MONPHOBA Q

Monofocal Yellow Tinted Hydrophobic Intraocular Lens



## DESCRIPTION

One-piece posterior chamber intraocular lens (hereinafter the IOL) from a yellow tinted acrylate copolymer with UV and pale blue light filter with refractive index 1,53. Modified C loop haptics. Material shape memory enables implantation through incision about 2 mm. Optical power range from -5,0 to +40,0 D in 0,5 D steps.

## INDICATIONS

Implantation to capsular bag to correct aphakia in adult patients during cataract or refractive lensectomy surgeries.

## CAUTION

Implantation is not recommended when the IOL may aggravate an existing condition, interfere with the diagnosis or the treatment of pathology, or present a risk to the sight. Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the benefit/risk ratio before implanting a lens in the following indications (list is not complete):

- Acute eye disease
- External or internal infection, or suspected infection
- Microphthalmos
- Corneal endothelial dystrophy
- Uveitis
- Proliferative diabetic retinopathy
- Clinically significant macular changes
- Severe optic atrophy
- Decompensated glaucoma
- Severe complications during surgery
- Capsular bag tear preventing safe IOL fixation
- Uncontrolled positive intraocular pressure
- Extremely shallow anterior chamber
- Choroidal hemorrhage
- Weakened zonula
- Color-vision deficiency
- Non-age-related cataract

## COMPLICATIONS

Cataract surgery complications include (but not limited):

- Increased intraocular pressure
- Corneal edema
- Hypopyon
- Iritis
- Pupillary block
- Capsular bag tear
- IOL damage during implantation
- Decentered or dislocated IOL
- Posterior capsular opacification
- Late IOL opacification
- Cystoid macular edema
- Retinal detachment
- Endophthalmitis
- Toxic anterior segment syndrome
- Halo a glare
- Residual refractive error

## WARNINGS

As with all surgical procedures, cataract surgery with IOL implantation presents risks. Patients with preoperative ocular conditions such as (but not limited to) glaucoma, amblyopia, diabetic retinopathy, previous retinal detachment, prior corneal transplantation may not achieve visual acuity of patients without these conditions, and vision may not improve. The surgeon must evaluate risk/benefit ratio of IOL implantation in every individual case.

Complications may lead to secondary interventions as (but are not limited to): IOL repositioning or replacement, vitrectomy, iridectomy, wound leak repair and retinal detachment repair. Some of the listed complications may require repeated surgical interventions and cause permanent loss of vision.

## DIRECTIONS FOR USE

- IOL can be implanted only by experienced eye surgeon or under his/her supervision.
- Examine the label on the unopened package for model, power and expiration date.
- Open the box and examine the integrity of inner pouch.
- DO NOT USE the IOL if the sterility has been compromised.
- Open the pouch and transfer the case to a sterile surgical table.
- Open the IOL holder and carefully grasp the IOL haptic by forceps for IOL manipulation to avoid optic damage
- All instruments used for IOL handling must be smooth with round edges, sterile and clean.
- Rinse the IOL thoroughly by BSS sterile intraocular irrigating solution. DO NOT RINSE the IOL by any other solutions.
- Prior to insertion, carefully examine the IOL to ensure the IOL is clean and transparent.
- Aspirate viscoelastic remnants, center IOL optic and conclude the surgery.
- In case of IOL damage during surgery we recommend IOL explantation.

## PACKAGING, STERILIZATION AND STORAGE

Dry IOL sterilized by ethylene oxide in plastic holder is sealed in pouch in paper box labeled by model, optical power, expiration date and serial number. Do not use IOL if the sterile package was damaged or already open. Store at temperature 5-25°C.

## OPTICAL POWER CALCULATION

A-constant labeled on the box is used for preoperative IOL power calculation in diopters. It is recommended to individualize the calculation for each surgeon.

## WARRANTY

Manufacturer guarantee IOL manufactured without defects and sterile until the labeled expiration date.

## DISCLAIMERS OF LIABILITY

The manufacturer will not be liable for any health consequences caused to patient as a result of:

- any implantation method or technique used by a surgeon to implant the IOL
- any prescription selection and use of the IOL for any individual patient or patient's condition

















## REPORTING

Adverse reactions and potentially sight threatening complications that may reasonably be regarded as IOL related, must be reported to the local distributor or manufacturer.

## RETURN OF DAMAGED LENS

Return the IOL in its original container to your local distributor with the model, optical power, batch number and serial number, and a reason for return

## SYMBOLS

-  Caution warning
-  See instruction for use
-  Do not reterilise
-  Do not reuse
-  Store between 5 & 25 °C
-  Store away from sunlight
-  Store in dry place
-  Manufacturer
-  Date of manufacture
-  Do not use if package damaged
-  Apply to the date
-  Batch code
-  Sterilized with ethylene oxide
-  Catalog number
-  Serial number
-  Conformity marking with Notified body No.

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