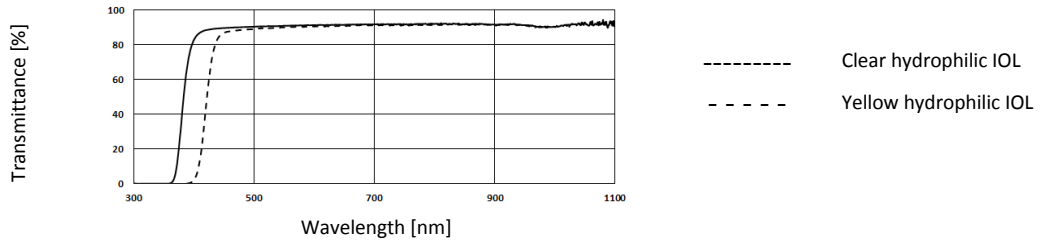
MEDICONTUR E-IFU

MEDICONTUR SML - SCHARIOTH MACULA LENS EN

DESCRIPTION

Consists of one, single piece, sterile, foldable acrylic intraocular lens (IOL) with UV-absorbent. Yellow IOLs have a blue-light filtering chromophore covalently bonded to the material (see Graph 1). These models are marked with 'Y' in the product code.

Graph 1: Average spectral transmittance of Medicontur IOLs



MODELS

Code	Material	Design
A45SML	hydrophilic	multifocal
A45SMY	hydrophilic	multifocal

PACKAGING

The hydrophilic lenses are supplied steam sterilized in a container filled with sterile water. The containers are packed in a protective blister.

EXPIRATION DATE

Medicontur IOLs are sterile unless their primary packaging is damaged. The expiry date is printed on the labels of the outer packaging and the protective blister or peel-pouch. Do not use an IOL after its expiry date.

INDICATIONS

Medicontur SML is intended to improve the near vision of pseudophakic patients suffering from the dry form of Age-related Macular Degeneration (AMD). The SML is designed solely to be implanted as a secondary intraocular lens into the ciliary sulcus of patients having a primary intraocular lens implanted in their capsular bag.

CONTRAINDICATIONS

Apart from non-specific contraindications related to any form of ocular surgery, the following non-exhaustive list must be respected:

- Microphthalmia
- Shallow anterior chamber (< 2.8 mm)
- Narrow angle, i.e. < Schaefer grade 2
- Congenital eye abnormality
- Pseudophakic patients with malpositioned or unstable capsular fixated intraocular lens
- Inability to achieve secure placement in the designated location e.g. due to absence of a secure pheriperal anterior capsule, absence of intact zonules, or irregular anatomy of the ciliary sulcus
- Active ocular diseases (chronic severe uveitis, proliferative diabetic retinopathy, chronic glaucoma not responsive to medication, iris atrophy, severe zonulopathy)
- Amblyopia
- Long-term anti-inflammatory treatment
- Children under the age of 18 years

- Corneal decompensation or diseases involving the central corneal or endothelial
- Active neovascular (wet) AMD
- Iris neovascularization
- Inadequate visualization of the fundus on preoperative examination
- Preoperative ineffective miotic pupillary reaction or non-mydriatic pupil size or more than 4 mm under photopic conditions
- Subluxation

COMPLICATIONS

As with any surgical procedure, there is risk involved. The following non-exhaustive list specifies the complications that have been associated with the implantation of IOLs:

- Corneal damage or edema
- Cystoid macular edema
- Secondary glaucoma
- Pupillary block
- Uveitis
- Iris trauma
- Intraocular infection
- IOL replacement or extraction
- Hemorrhage
- Postoperative opacification/calcification of the IOL
- Endophthalmitis
- Asthenopic discomfort, adaptional difficulties
- Reduced contrast sensitivity
- Reduced vision at night or in poor visibility conditions
- Perception of halos or radial lines around point sources of light
- Dissatisfactory visual outcome due to incorrect IOL refraction

WARNINGS

- Examine the package labels carefully for information about the lens model, power and expiration date. Lenses should not be used after the expiration date.
- Do not resterilize or reuse the lens by any method.
- Do not use the IOL if the packaging is damaged or wet and lens sterility may have been compromised.
- Store the unopened IOL box in a dry place, away from moisture and direct sunlight at room temperature (15-35°C).
- Do not use hydrophilic IOLs if there is no fluid in the lens container.
- The storage fluid must not be used.
- A temporary opaqueness of the lens may occur in case of a considerable change of temperature. This phenomenon does not damage the lens material and the lens reverts to transparency after some time.
- A high level of surgical skills is required to implant intraocular lenses. The surgeon should have observed and/or assisted at numerous implantations and successfully completed one or more courses on IOL implantation before attempting to implant intraocular lenses.
- IOLs should be handled carefully to avoid damage to the lens optics or haptics. Non-toothed, polished instruments should be used, without grasping the optical area with forceps.

- Patients should be advised that unexpected outcomes may necessitate additional surgical intervention.
- For optimal results, aim to achieve perfect IOL centration.
- Do not implant the SML into the capsular bag.
- The product or its waste material should be disposed of in accordance with local/national regulations and requirements.

DIRECTIONS FOR USE

1. Open the outer package to remove the protective peel-pouch or blister pack and verify that the IOL container information is consistent with the outer package labeling (e.g. power, model, SN).
2. Open the protective peel-pouch or blister and remove the lens container from the packaging in a sterile environment. Carefully open the cap and remove the lens holder from the fluid.
3. Transfer the lens, using sterile equipment to an appropriate loading device. Rinse the IOL with sterile Balanced Salt Solution. For loading and injection of the lens follow the Instructions for Use of the injector.
4. Unlike capsular bag implanted lenses, this IOL has to be folded in the opposite direction. Position the lens in the loading bay of the cartridge in a “reverse-U” configuration (∩). This ensures that the lens is folded and bent upwards above the haptics which are positioned securely under the edge of the two grooves of the cartridge. Folding this way will ensure that the lens will unfold with the leading haptics downwards into the ciliary sulcus.
5. Various surgical procedures can be utilized. The surgeon should select a technique that is appropriate for the patient.
6. Hydrophilic IOLs should not be kept in open air for longer than 1 minute. Neither type of IOL should be in folded condition for longer than 3 minutes. If these time limits have been exceeded the lens should be discarded.

LIABILITY

Medicontur does not bear any responsibility for improper model selection by the physician, for improper handling, use, surgical technique applied or for any other iatrogenic error caused by the implanting surgeon.

PATIENT CARD

One of the self-adhesive labels with the IOL data printed on it is designed to be placed on the Patient Card, also enclosed in the packaging. This Patient Card should be handed over to the patient for future reference allowing the patient to identify the surgeon and the type of IOL implanted.

SYMBOLS

CE 0120 — CE certified	Keep dry	Do not re-use
Keep away from sunlight	Consult instructions for use	Do not resterilize
SN — Serial number	Use by date	STORE AT ROOM TEMPERATURE — Store at room temperature

 Do not use if package is damaged	 Manufacturer	 Do not freeze
 Sterilized using steam or dry heat		

MANUFACTURER

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Please report any adverse event or complaint to Medicontur's Quality Assurance at QA@medicontur.hu.

LAST UPDATE: December 2017

This document is executed in the English language. In the event of any inconsistencies, the English version shall prevail.