**MEDICONTUR "FLEX" HYDROPHOBIC MONOFOCAL INTRAOCULAR LENSES PRELOADED IN A SINGLE USE INJECTOR**

**DESCRIPTION**

Consists of one, single piece, sterile, foldable acrylic intraocular lens (IOL) with UV-absorbent, preloaded in an assembled injector. 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. Different models are controlled individually for their optical and mechanical properties.

The parts of the injector are: injector body, adapter, rotatable ring, cartridge, stopper, plunger with a soft tip, spring.

Graph 1: Average spectral transmittance of Medicontur IOLs

<table>
<thead>
<tr>
<th>Transmittance [%]</th>
<th>Wavelength [nm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow hydrophobic IOL</td>
<td>400-800</td>
</tr>
<tr>
<td>Clear hydrophobic IOL</td>
<td>400-800</td>
</tr>
</tbody>
</table>

**MODELS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand</th>
<th>Material</th>
<th>Design</th>
<th>Estimated corneal incision size</th>
</tr>
</thead>
<tbody>
<tr>
<td>877PA</td>
<td>Bi-Flex</td>
<td>hydrophobic</td>
<td>monofocal</td>
<td>2.2 mm</td>
</tr>
<tr>
<td>877PAY</td>
<td>Bi-Flex</td>
<td>hydrophobic</td>
<td>monofocal</td>
<td>2.2 mm</td>
</tr>
<tr>
<td>860PA</td>
<td>Z-Flex</td>
<td>hydrophobic</td>
<td>monofocal</td>
<td>2.2 mm</td>
</tr>
<tr>
<td>860PAY</td>
<td>Z-Flex</td>
<td>hydrophobic</td>
<td>monofocal</td>
<td>2.2 mm</td>
</tr>
</tbody>
</table>

**PACKAGING**

The IOL is packaged in the injector and the entire system is packaged in a protective blister, sterilized by ethylene oxide.

**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**

Correction of aphakia after surgical cataract extraction in adult patients. Medicontur "FLEX" IOLs are intended for replacement of the human crystalline lens in the capsular bag, in the posterior chamber of the eye.

**CONTRAINDICATIONS**

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

- Choroidal hemorrhage
- Significant vitreous loss
- Extremely shallow anterior chamber
- Posterior capsular rupture
- Severe corneal dystrophy
- Severe optic nerve atrophy
- Zonular separation

- Color vision deficiencies
- Uncontrolled glaucoma
- Chronic uveitis
- Diabetic retinopathy
- Retinal detachment
- Recurrent anterior or posterior segment inflammation of unknown etiology
- Clinically significant macular/RPE change

**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
- Dissatisfactory visual outcome due to incorrect IOL refraction

**PRECAUTIONS AND 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 re-use the lens or any part of the system 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).
- 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.

**PREOPERATIVE CALCULATION OF IOL POWER**

IOL power should be determined preoperatively based on proper biometry data using the formulae available in the literature. The A-constant value specified on the outer label is presented as a guideline. It is advised that surgeons personalize the constants they use based on their surgical techniques, equipment and post-operative results.

**DIRECTIONS FOR USE**

1. Open the outer package to remove the blister containing the injector system and verify that the information on the blister is the capsular bag, in the posterior chamber of the eye.
2. Open the blister and remove the injector system with the IOL in a sterile environment.
3. Fully introduce the cannula (23G) of a syringe filled with viscoelastic material into the small aperture indicated with ‘1’ (Fig. 1), maintaining a slight pressure on the cannula tip. Inject a sufficient quantity of dispersive viscoelastic solution (preferably HPMC) through the aperture. The injected quantity of visco is sufficient as soon as the two flows (drops) of the viscoelastic solution meet on top of the lens (become confluent).

4. Turn the transparent rotatable ring as indicated by the flat arrow marked with ‘2’ counterclockwise by 90 degrees until it snaps into place with a distinct “click” (Fig. 2a)

5. Remove the red stopper indicated with ‘3’ by pulling and discard it (Fig. 2b).

6. Push the plunger forward in a slow, controlled manner. Anticipate a slight initial resistance. Excessive resistance could indicate a trapped lens.

7. With the nozzle tip bevel facing down, inject the IOL applying continuous pressure on the plunger.

8. When the lens exits the cartridge nozzle, stop pressing the plunger and withdraw the cartridge nozzle tip from the eye.

NOTE
- Balanced Salt Solution alone should not be used as lubricant
- When pressing the plunger, too much resistance may indicate a trapped lens
- Do not stop the injection after you have started implanting the lens. The entire process should be one continuous process without interruption.
- If the IOL blocks the injector system, discard the injector.
- Discard the injector after use.

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 and allows the patient to identify the surgeon and the type of IOL implanted.

SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE</td>
<td>CE certified</td>
</tr>
<tr>
<td>Store dry</td>
<td>Store dry</td>
</tr>
<tr>
<td>SN</td>
<td>Serial number</td>
</tr>
<tr>
<td>SN</td>
<td>Use by date</td>
</tr>
<tr>
<td>SN</td>
<td>Store at room temperature</td>
</tr>
<tr>
<td>SN</td>
<td>Single use</td>
</tr>
<tr>
<td>SN</td>
<td>Do not re-sterilize</td>
</tr>
<tr>
<td>SN</td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td>SN</td>
<td>Manufacture</td>
</tr>
<tr>
<td>SN</td>
<td>Do not freeze</td>
</tr>
<tr>
<td>SN</td>
<td>Sterilized by steam heat autoclave method</td>
</tr>
<tr>
<td>SN</td>
<td>Sterilized by ethylene oxide</td>
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</tbody>
</table>

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