MEDICONTUR “FLEX” PRELOADED HYDROPHILIC INTRAOCULAR LENSES

DESCRIPTION

Consists of one, single piece, sterile, preloaded, 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. Different models are controlled individually for their optical and mechanical properties.

EXTENDED DESCRIPTION - TORIC MODELS

In case of monotoric lenses the toric surface is on the posterior side, whereas in case of bitoric lenses both sides are toric.

EXTENDED DESCRIPTION - DIFFRACTIVE PROGRESSIVE MODELS

The anterior surface is the apodized, diffractive side of the lens. The added power for near vision is indicated on the label. For the defocus curves see Graph 2.

Graph 1: Average spectral transmittance of Medicontur IOLs

![Graph 1](image1.png)

Wavelength [nm]

Graph 2: Average defocus curves by pupil size for Medicontur Diffractive Progressive IOLs (with +3.5 D Add)

![Graph 2](image2.png)

Refraction [D]

NOTE

Medicontur Preloaded Hydrophilic Intraocular Lenses are dedicated for use uniquely with the MEDJET PIL-MA single use injector system. The two major components of one system are packaged individually. Before using the devices please read both Instructions for Use carefully.
MONOFOCAL MODELS

<table>
<thead>
<tr>
<th>Code</th>
<th>Brand</th>
<th>Material</th>
<th>Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>677P</td>
<td>Bi-Flex</td>
<td>hydrophilic</td>
<td>monofocal</td>
</tr>
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<td>677PY</td>
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<td>monofocal</td>
</tr>
<tr>
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<td>monofocal</td>
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</tr>
<tr>
<td>640PY</td>
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TORIC MODELS

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<td>Bi-Flex T</td>
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</tr>
<tr>
<td>677PTY</td>
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<td>monotoric</td>
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<td>Z-Flex T</td>
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DIFFRACTIVE PROGRESSIVE MODELS

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<tr>
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<td>Q-Flex M</td>
<td>hydrophilic</td>
<td>diffractive progressive</td>
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DIFFRACTIVE PROGRESSIVE TORIC MODELS

<table>
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<tr>
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<th>Design</th>
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</thead>
<tbody>
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<td>diffractive progressive monotoric</td>
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<tr>
<td>690PMTY</td>
<td>Z-Flex MT</td>
<td>hydrophilic</td>
<td>diffractive progressive monotoric</td>
</tr>
</tbody>
</table>

PACKAGING

The hydrophilic lenses are supplied steam sterilized in a container filled with 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**

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.

**EXTENDED INDICATIONS - TORIC MODELS**

- Toric IOLs are recommended for patients who aspire to have improved uncorrected distance vision and reduction of residual refractive cylinder.
- Toric design Medicontur IOL models are implanted in astigmatic eyes.

**EXTENDED INDICATIONS - DIFFRACTIVE PROGRESSIVE MODELS**

- Diffractive Progressive IOLs are recommended for patients who aspire to have near and distance vision with increased spectacle independence
- Multifocal design Medicontur IOL models are implanted in presbyopic eyes regardless of whether there is cataract or not.

**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 changes

**EXTENDED CONTRAINDICATIONS - TORIC & DIFFRACTIVE PROGRESSIVE MODELS**
In case of patients who underwent previous refractive treatment – for example any kind of keratoplasty – the indication should be determined very carefully.

EXTENDED CONTRAINDICATIONS - DIFRACTIVE PROGRESSIVE MODELS

- Individuals who drive at night for a living or whose occupation or hobbies depend on good night vision
- Individuals who need very good near vision in semidarkness
- Individuals who are professional or non-professional pilots
- Keratoconus
- Age-related macular degeneration
- Monocular patients
- Any eye disease in which postoperative visual acuity is not expected to be better than 0.5 (e.g. Amblyopia, nystagmus, retinitis pigmentosa, aniridia, eccentric pupil)

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 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).
- 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. Nontoothed, polished instruments should be used, without grasping the optical area with forceps.
- Patients should be advised that unexpected outcomes may necessitate additional surgical intervention.

PRECAUTIONS AND WARNINGS - TORIC MODELS

- Prior to surgery mark the operative eye with at least two reference points or use an operating microscope that provides an axis guide.
- For optimal results, the surgeon must ensure the correct placement and orientation of the lens within the capsular bag. The posterior surface of the IOL is marked with 2 linear indentations at the optic-haptic junctions that identify the flat meridian of the IOL. The cylinder axis marks should be aligned with the post-incision steep corneal meridian.
- For optimal results, aim to achieve perfect IOL centration.
- Carefully remove all viscoelastic material from both sides of the lens. Residual viscoelastic material may cause complications including lens rotation resulting in the misalignment of the IOL, which compromises astigmatic correction.

PRECAUTIONS AND WARNINGS - DIFFRACTIVE PROGRESSIVE MODELS

- Manage patient selection and operative technique carefully to ensure that the total postoperative corneal astigmatism does not exceed 1.5 diopters. Patients with pupil size less than 2.5 mm may not obtain any near vision benefit.
- For optimal results, aim to achieve perfect IOL centration.
- Some patients may experience reduced contrast sensitivity as compared to monofocal IOLs.
- Some patients may experience visual effects with the Multifocal IOLs because of the superpositioning of focused and unfocused images. Visual effects may include the perception of halos or radial lines around point light sources under low illumination conditions.
- Patients should be advised that unexpected outcomes could lead to continued spectacle dependence.
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. For Toric IOLs, the use of a computerized/web-based toric calculator is highly recommended to ensure the best optical outcome. For further information please refer to http://toriccalculator.net or http://www.medicontur.com.

For Diffractive Progressive lenses target emmetropia.

DIRECTIONS FOR USE

1. Open the outer package to remove the protective blister pack and verify that the IOL container information is consistent with the outer package labeling (e.g. power, model, SN). At the same time ensure that the appropriate, unexpired, sterile and unused MEDJET PIL-MA injection system is available.
2. Open the blister at the marked end and remove the lens container in a sterile environment.
3. Remove the peel-off aluminum foil from the wet lens container while holding the container horizontally.
4. For loading and injection of the lens please refer to the Instructions for Use enclosed with the MEDJET PIL-MA injection system.

NOTE

Stick a self-adhesive label on the Patient Card enclosed. This 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>Icon</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE 0120</td>
<td>CE certified</td>
</tr>
<tr>
<td>☂️</td>
<td>Store dry</td>
</tr>
<tr>
<td>☑️</td>
<td>Single use</td>
</tr>
<tr>
<td>☂️</td>
<td>Keep away from sunlight</td>
</tr>
<tr>
<td>📖</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>☑️</td>
<td>Do not resterilize</td>
</tr>
<tr>
<td>SN</td>
<td>Serial number</td>
</tr>
<tr>
<td>🕒</td>
<td>Use by date</td>
</tr>
<tr>
<td>☑️</td>
<td>Store at room temperature</td>
</tr>
<tr>
<td>☑️</td>
<td>Do not freeze</td>
</tr>
<tr>
<td>🚧</td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td>📦</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🚧</td>
<td>Do not freeze</td>
</tr>
<tr>
<td>🚧</td>
<td>Sterilized by steam heat autoclave method</td>
</tr>
<tr>
<td>🚧</td>
<td>Sterilized by ethylene oxide</td>
</tr>
</tbody>
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### MANUFACTURER

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Fax: +36 23 56 55 56

Please report any adverse events or complaints to Medicontur’s Quality Assurance at QA@medicontur.hu.

### LAST UPDATE: 06 2015