DEVICE SPECIFICATIONS

Product code: i01

Figure 1. Tridimensional view of the lens.

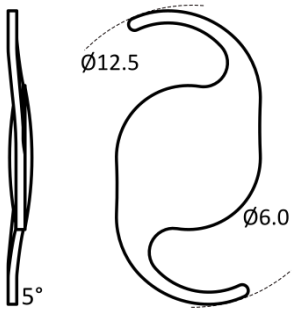

Figure 2. Picture on the label.

DESCRIPTION OF THE DEVICE

Hydrophilic aspheric monofocal intraocular lens with a proven C-loop design. The shape of the two positioning loops, paired with the elastic characteristics of the material, promotes the precise centering of the lens and the automatic adaptation to different diameters of the capsular bag.

Material	*FIL* - PolyHema with 25% H_2O and biocompatible UV filter
Optics	Aspheric monofocal
Optic plate diameter	6.00 mm
Total diameter	12.50 mm
Haptic angulation	5°
Refraction index	1.461 (546 nm, 20°C)
Available Diopters	-5.00 D → +40.00 D
Step	0.50 D
Suggested A Constant	118.90 (SRK/T Optical)
Suggested Injector	Medicel Accuject 2.1 or Viscoject ECO 2.2 up to +32.00 D
	Medicel Accuject DUAL 2.6 over +32.00 D

CLASSIFICATION

Sterile Medical Device, single use, Class II B implantable. Annex IX, Rule 8, compliant with the Directive 93/42/EEC, implemented in Italy with Legislative Decree No. 46 of 24/02/1997 as an amendment to Directive 2007/47 EC implemented with Legislative Decree 37 of 25/01/2010.

CERTIFICATION

EC Certification released by TÜV SÜD, notified body n. 0123. Certification n. G1 026633 0022 Rev. 01.

REGISTRATION
Registered in the Italian Health Ministry with RDM Code: 217521. EMDN Code: "P030102090202".

MANUFACTURER
SOLEKO S.p.A, in the factory located in via Ravano snc, 03037 Pontecorvo (FR), Italy.

DIRECTION OF USE
The implantation of the hydrophilic intraocular lens FIL 60 is indicated in the treatment of aphakia. The FIL 60 intraocular lenses are designed to be implanted in the capsular bag.

MATERIAL AND COMPATIBILITY
Hydrophilic PolyHema with 25% H2O and biocompatible ultraviolet filter (UV). Doesn't contain latex. Compatible with magnetic resonance.

MANUFACTURING TECHNOLOGY
Semi-moulding with precision lathing and milling.

STERILIZATION
Sterilized in steam autoclave. Not re-sterilizable by any method.

EXPIRY AND STORAGE
Expiry is set at 35 months. Store at a temperature not lower than +18°C.

PRIMARY PACKAGING
The product is supplied in double sterile barrier. The lens is kept in double-distilled non-pyrogenic water inside a PP blister sealed by an aluminium barrier (primary sterile barrier). The blister is contained in a heat-sealed Tyvek® envelope (secondary sterile barrier).

SECONDARY PACKAGING
Cardboard case with sealed flaps and tear opening. Contents: packaging containing the product, information sheet, patient card, series of labels for traceability.

Figure 3. Lens packaging.

DEVICE DISPOSAL
Dispose the product, if unused or after use, respecting the internal hospital regulations regarding the disposal of infected or potentially infected medical devices.

CE 0123