REVIEW
PREMIUM IOL

FIL SSF
Sutureless Scleral Fixation

SOLEKO
IOLDIVISION
ITALIAN OPHTALMIC LAB

# DEVICE SPECIFICATIONS

Product code: i71

**Figure 1.** Tridimensional view of the lens.

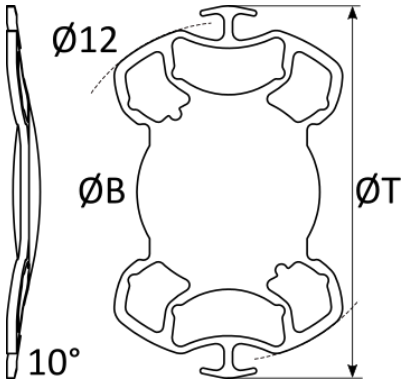


**Figure 2.** Picture on the label.

## DESCRIPTION OF THE DEVICE

Intraocular lens precisely designed for scleral fixation. The presence of harpoons guarantees a stable sutureless trans-scleral anchoring.

| | |
|---|---|
| Optic plate diameter (ØB) | 6.5 mm |
| Total diameter (ØT) | 13.2 mm |
| Haptic angulation | 10° |
| Refraction index | 1.461 (546 nm, 20°C) |
| Available Diopters | -5.00 D → +35.00 D |
| Step | 0.50 D |
| Suggested A Constant | 118.7 (SRK/T Optical) |
| Suggested Injector | Medicel Accuject 2.1 up to +32.00 D |
| | Medicel Accuject 2.2 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: 1399102. CND Classification: "P030102090102".

## MANUFACTURER

SOLEKO S.p.A – Menicon Group, in the factory located in Pontecorvo (FR), 03037 Ravano snc street.

## DIRECTION OF USE

The implant of the hydrophilic intraocular lens FIL SSF is suggested in the correction of aphakic eyes, in which adequate capsular support is absent. Hydrophilic intraocular lenses FIL SSF are designed to be implanted in the ciliary sulcus in case of absent capsular support, through the anchoring of self-blocking harpoons in scleral pockets and consequent covering of the harpoons by the scleral pockets (minimum suggested dimension 3.5 mm X 3.5 mm).

## MATERIAL AND COMPATIBILITY

Hydrophilic PolyHema with 25% $H_2O$ and biocompatible ultraviolet filter (UV). Doesn't contain latex. Compatible with magnetic resonance.

## MANUFACTURING TECHNOLOGY

Partial-moulding with precision lathing and milling.

## STERILIZATION

In steam autoclave. Not re-sterilizable by any method.

## EXPIRY AND STORAGE

Expiry is set at 36 months. Store at a temperature not less than +18°C.

## PRIMARY PACKAGING

The product is supplied in double sterile barrier. The lens is kept in double-distilled apirogenic water inside a PP blister sealed by an aluminum 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: sterile 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.

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