



FIL SSF

Sutureless Scleral Fixation

DEVICE SPECIFICATIONS

Product code: i71

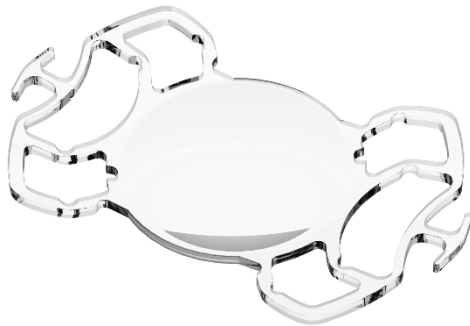


Figure 1. Tridimensional view of the lens.

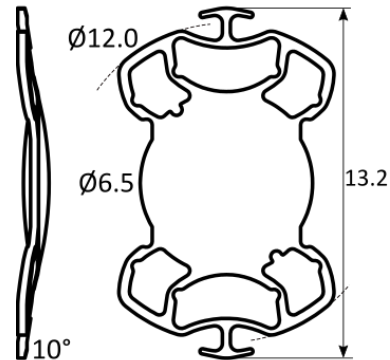


Figure 2. Picture on the label.

DESCRIPTION OF THE DEVICE

The *FIL SSF* is a hydrophilic intraocular lens with aspherical optic designed for scleral fixation to restore emmetropia in cases of insufficient or absent capsular support. The presence of harpoons guarantees a stable sutureless trans-scleral anchoring. It is compatible with microincisions and superior stability against tilt and rotation is assured by a total diameter of 13.20 mm with four points of support. Haptic angulation of 10° assures a physiological positioning of the lens reducing the risk of pupillary block.

Optic plate diameter (ØB)	6.5 mm
Total diameter (ØT)	13.2 mm
Haptic angulation	10°
Material	FIL - PolyHema with 25% H ₂ O and biocompatible UV filter
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, in the factory located in via Ravano snc, 03037 Pontecorvo (FR), Italy.

DIRECTION OF USE

The implant of the *FIL SSF* is suggested in the correction of aphakic eyes, in which adequate capsular support is absent. The *FIL SSF* is intended to be placed in the ciliary sulcus, in the pars plicata or in the anterior pars plana, through the anchoring of self-blocking harpoons inside scleral pockets. The device is intended for use in adult patients with advanced cataracts, either with insufficient or absent capsular support or with insufficient zonular support.

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

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

EXPIRY AND STORAGE

Expiry is set at 35 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 apyrogenic 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: 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.

