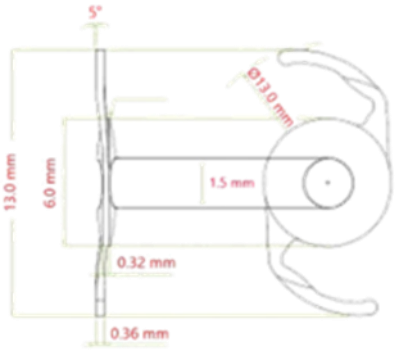
Technical Data Sheet IOL AMD

Product code: ISP60KN
Model: IOL AMD
Manufacturer: Soleko SpA (in esclusiva per SubVision S.r.l. ¬ Via G. da Procida, 6 ¬ 20149 Milano – Italia)
Distributor: Md Tech Srl - Via Fratelli Bandiera, Ncc - 80026 Casoria (Na), Campania Italia
Intended Use: Maculopathy surgery
Use: Intraoperative ophthalmic use
Italian Registration Number: 132474

One-piece hydrophilic acrylic lens made for pseudo-phakic patients suffering from maculopathy. At the center of the IOL a small diameter area with highly positive power has been obtained, which can only be activated by approaching the writing at a distance of about 10cm.



General Features

Material	Hydrophilic acrylic, biocompatible with ocular tissue
Central power	+12.0D
Incision	from 2.2mm with single use Medicel injector

Optical Features

Optic Diameter	6.0mm
Lenticule diameter	1.5mm
Total Diameter	15.0mm
Sferical Aberration	-0,26 µm
Color	Clear
Indice di Rifrazione	1,46
UV Filter	Present

// Haptics Features

Type	Optical disc and haptics without profile discontinuity
Haptic Angulation	7° for a long term better stability in the sulcus

// Other Specifications

Reference Standard	Directive 93/42 CEE, UNI EN ISO:11979
Class	II b Notified Body n°0123, TÜV SÜD PRODUCT SERVICE, certif. N° G1 026633 0022 Rev. 01
Control Performed	DIOPTER , MTF, Cosmetic
Packaging	Each lens is packed in a lens case in WFI contained in a blister of PETG and Tyvek (primary packaging) and in carton box (secondary packaging) in kit with a MEDICEL injector.
Product Type	Medical device in compliance with the current legislation
Compatibility With Solutions	Product can be used with hyaluronic acid, balanced salt solution. It must not be used with acid or melted with other substances.
Shelf Life and Sterilization Method	Product has 36 months of validity from sterilization date and however until expiry date reported on labels. Steam sterilized in conformity to UNI EN ISO 17665. The injector is sterilized with EtO in accordance with UNI EN ISO: 11135-1 / 2. The product is NOT RESTERILISABLE.
Tests	In vitro cytotoxicity tests, allergic sensitization tests on guinea pigs, eye irritation tests on guinea pigs, product stability tests have been carried out on the product in the experimental phase (reports available in the company)
Presence of Latex	No
Storage	Store at ambience condition, in dry place without humidity. Temperature must be in the range +5°C and+45°.
Information Reported on the Packaging	Batch number, expiry date, serial number, sterilization, manufacturer, CE mark.