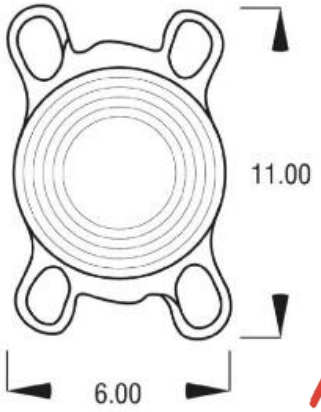
Technical Data Sheet I-Stream Trifocal Plus

Product code: ISP60L + diopter
Model: I-Stream Trifocal plus
Manufacturer: Md Tech Srl - Via Fratelli Bandiera, Ncc - 80026 Casoria (Na), Campania Italia
Intended Use: Cataract surgery
Use: Intraoperative ophthalmic use
Italian Registration Number: 125034

One-piece trifocal lens with hydrophilic / hydrophobic copolymer preloaded in kit with Medicel injector, with biconvex surface with asphericity. Quadrilateral shape with fenestrated haptics.



General Features

Material	Hydrophilic / hydrophobic copolymer with UV filter with 25% water content, biocompatible.
Lens Geometry	Biconvex profile and variable optics as the dioptric power varies, Square Edge 360 °
Dioptric Range	from -5.0D to + 10.0D with increment of 1D; from +10.5D to +31.5D with increment of 0.5 Dpt; from +32.0 to 40.0 with increment of 1D
Additional Power	+3.5 D
Intermediate value	+1.75 D
Incision	from 1.8mm with preloaded injector

Optical Features

Optic Diameter	6.0mm
Total Diameter	11.0mm
Sferical Aberration	-0,26 µm
Color	Natural Yellow
Refractive Index	1,46
UV Filter	Natural Yellow UV CUT OFF < 2% @420nm
A Costant	118.2
Constant with Ulib System	SRK/T = 118,7; SRK/2 = 118,9; Holladay1 sf = 1,10; Holladay2 = 5,082; Barrett= +1,46 HofferQ pACD = 4,88; Haigis a0 = 0,647; a1 = 0,40; a2 = 0,10

// Haptics Features

Type	Optical disc and haptics without profile discontinuity
Angulation	0° / 5°

// Other Specifications

Reference Standard	Directive 93/42 CEE, UNI EN ISO:11979
Class	II b Certiquality Srl, Notified Boby n°0546, certif. N.18539/1/I
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 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	Information Reported on the Packaging