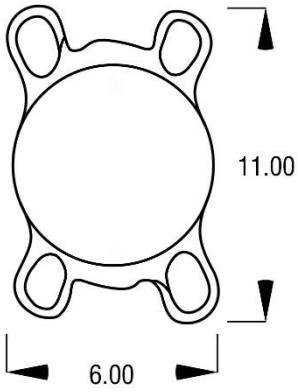
Technical data Sheet I-Stream P

Product code: ISP60P + diopter
Model: I-Stream P
Manufacturer: Md Tech Srl - Via Fratelli Bandiera, Ncc - 80026 Casoria (Na), Campania Italia
Intended Use: Cataract surgery
Use: Intraoperative ophthalmic use
Italian Registration Number: 1804032

One-piece preloaded hydrophobic acrylic lens with aspherical front surface with Glare Stop Barrier filter. Quadrilateral shape with fenestrated haptics



General Features

Material	Hydrophobic acrylic with UV filter with water content <1%, biocompatible with eye tissue
Lens Geometry	Biconvex optic, Monofocal, Aspheric, Square Edge 360°.
Dioptric Range	from -10.0D to + 10.0D with increment of 1D; from +10.5D to +30.5D with increment of 0.5 Dpt; from +31.0 to 40.0 with increment of 1D
Incision	from 2,2mm with preloaded injector

Optical Features

Optic Diameter	6.0mm
Total Diameter	11.0mm
Sferical Aberration	-0,26 µm
Color	Clear
Refractive Index	1,56
UV Filter	White UV CUT OFF < 10% @370nm
A Costant	118
Constant with Ulib System	SRK/T = 118,8; SRK/2 = 119,1; Holladay1 sf = 1,66; Holladay 2 = 5,432; Barrett = 1,78 HofferQ pACD = 5,45; Haigis a0 = 1,26; a1 = 0,40; a2 = 0,10

// Haptics Features

Type	Optical disc and haptics without profile discontinuity
Haptic Angulation	5° for a long term better stability in the capsular bag

// 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 preloaded in a push type injector packed in a polypropylene blister closed in a tyvek pouch. Each pouch is contained in a carton box with administrative label.
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 60 months of validity from sterilization date and until the date declared on label. Sterilized with EtO according to UNI EN ISO 11135. Product cannot be re-sterilized.
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.