

Technical Data Sheet I-Stream Toric

Product Code: ISP60QT + dioptr+ cylinder

Model: I-Stream Toric

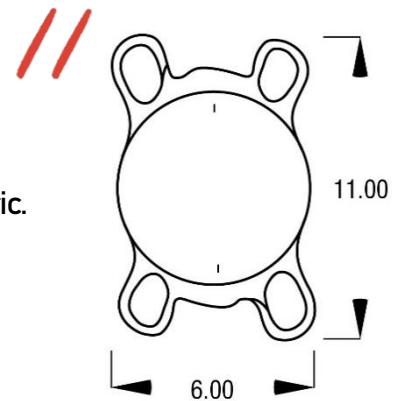
Manufacturer: Md Tech Srl - Via Fratelli Bandiera, Ncc - 80026 Casoria (Na), Campania Italia

Intended use: Chirurgia della cataratta

Use: Intraoperative ophthalmic use for the elimination of the astigmatism defect

Italian Registration Number: 1267988

Acrylic copolymer hydrophilic/hydrophobic single-piece toric iol aspheric.
Quadrilateral shape with fenestrated haptics.



// General Features

Material	Hybrid (hydrophilic with hydrophobic surface), biocompatible with eye tissue
Lens Geometry	Biconvex profile and variable optics as the dioptric power varies, Square Edge 360 °
Dioptric Range	from +9.0D to +30.0D with increment of 0.5D
Cylinder Range	from 0.75 to 7,50 and, on request, until 12
Incision	from 1,8mm with sigle use 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 = 1,60; Holladay2 = 5,374; Barrett = 1,73 HofferQ pACD = 5,39; Haigis a0 = 1,25; a1 = 0,40; a2 = 0,10

// Haptics Features

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

// Other Specifications

Reference Standard	Directive 93/42 CEE, UNI EN ISO:11979
Class	II b Certiquality Srl, Notified Body 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).
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. Product is not re-sterilizable.
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 ambient 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.

