

## Technical Data Sheet I-Stream Diffrax

Product code: ISP60D + dioptr

Model: I-Stream Diffrax

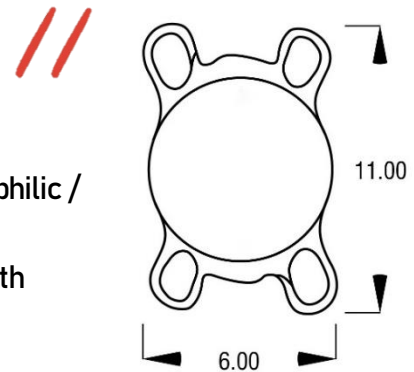
Manufacturer: Md Tech Srl - Via Fratelli Bandiera, Ncc - 80026 Casoria (Na), Campania Italia

Intended Use: Cataract surgery

Use: Intraoperative ophthalmic use

Numero di Repertorio: 1542884

One-piece multifocal diffrax extended depth focus lens with hydrophilic / hydrophobic copolymer preloaded in kit with Mediceal injector, with biconvex surface with negative asphericity. Quadrilateral shape with fenestrated haptics.



### // General Features

<b>Material</b>	Hydrophilic / hydrophobic copolymer with UV filter, biocompatible with eye tissue
<b>Lens Geometry</b>	Multifocal diffrax profile with Extended Depth Focus (EDOF), Square Edge 360 °, no rings
<b>Diopter Range</b>	from 0.0D to 40.0D with increment of 0,5 from 10.0D to 28.0D
<b>Additional Power</b>	+3.0 D to improve intermediate vision
<b>Incision</b>	from 2.0mm with preloaded injector

### // Optical Features

<b>Optic Diameter</b>	6.0mm
<b>Total Diameter</b>	11.0mm
<b>Spherical Aberration</b>	-0,26 μm
<b>Color</b>	Natural Yellow
<b>Refractive Index</b>	1,46
<b>UV Filter</b>	Natural Yellow UV CUT OFF < 2% @420nm
<b>A Costant</b>	118.2
<b>Constant with Ulib System</b>	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

## // Caratteristiche Anse

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

## // Other Specifications

<b>Reference Standard</b>	Directive 93/42 CEE, UNI EN ISO:11979
<b>Class</b>	II b Certiquality Srl, Notified Body n°0546, certif. N.18539/1/I
<b>Control Performed</b>	DIOPTER , MTF, Cosmetic
<b>Packaging</b>	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.
<b>Product Type</b>	Medical device in compliance with the current legislation
<b>Compatibility With Solutions</b>	Product can be used with hyaluronic acid, balanced salt solution. It must not be used with acid or melted with other substances.
<b>Shelf Life and Sterilization Method</b>	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.
<b>Tests</b>	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)
<b>Presence of Latex</b>	No
<b>Storage</b>	Store at ambience condition, in dry place without humidity. Temperature must be in the range +5°C and +45°.
<b>Information Reported on the Packaging</b>	Information Reported on the Packaging

