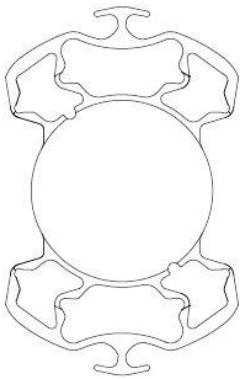
md tech srl

Technical Data Sheet Carlevale IOl hi- Tech

Product code: ISP60VL + diopter
Model: Carlevale IOl hi- Tech
Assembler: Md Tech Srl - Via Fratelli Bandiera, Ncc - 80026 Casoria (Na), Campania Italia
Intended Use: Intraoperative ophthalmic use



First and only scleral fixation lens without suture with self-locking anti-extrusion insert, injectable, for aphakic eyes in which there is no capsular support, or for patients suffering from Marfan syndrome or other clinical conditions for which other types of intraocular lenses are not indicated.

General Features

Material	Hybrid (hydrophilic/ hydrophobic copolymer), biocompatible with eye tissue
Dioptric Range	From 10.00Dpt to 30.00Dpt with step of 0,50Dpt
Incision	from 2.2mm with single use Medicel injector
Lens Geometry	Monofocal

Optical Features

Optic Diameter	6.5mm
Total Diameter	13.4mm
Color	Natural yellow
UV Filter	Natural Yellow UV CUT OFF < 2% @420nm
Refractive Index	1,46
A Costant U/S	118,0
Constant with Ulib System	SRK/T = 118,5; SRKII = 118,7; Holladay1 sf = 1,42; Holladay 2 = 5.257; Barrett = 1.62 HofferQ pACD = 5,20; Haigis a0 = 1,589; a1 = 0,400; a2 = 0,100

Haptics Features

Type	Optical disc and haptics without profile discontinuity
Haptic Angulation	10° for a long term better stability

// Other Specifications

Reference Standard	Directive 93/42 CEE, UNI EN ISO:11979
Class	II b
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.