

Technical Data Sheet Synergy visc (1.0- 1.2—1.4-1.6-1.8-2.0) viscoelastic with cannula

Product code: SYNK10 -SYNK12 – SYNK14 – SYNK16 – SYNK18 – SYNK20

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

Manufacturer cannula: Sterimedix

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

Description: Synergy visc is a viscoelastic solution based on Sodium Hyaluronate with pharmaceutical grade purity, registered as a medical device for intraocular injection use.

Intended Use: Synergy visc is an indicator in eye surgery of the anterior segment including the cataract removal, intraocular lens insertion, corneal transplant, glaucoma and retinal detachment.

Synergy visc can be used to protect and lubricate intraocular lenses and injection systems beforehand the installation of the same

// General Features

Packaging	The package contains 1 27 G sterile cannula needle and 1 glass syringe sterile disposable, pre-filled with 1.1 ml of product.
Composition	Sodium Hyaluronate at different concentrations (18mg/mL – 16mg/mL -14mg /mL), Sodium Chloride, Disodium Hydrogen Phosphate Dodecahydrate, Sodium Dihydrogen Phosphate Dihydrate and Water for injections

// Technical Features

	1.0%	1.2%	1.4%	1.6%	1.8%	2.0%
pH	6.8 – 7.6	6.8 – 7.6	6.8 – 7.6	6.8 – 7.6	6.8 – 7.6	6.8 – 7.6
Osmolality	300 – 350 mOsm/Kg	300 – 350 mOsm/Kg	300 – 350 mOsm/Kg	300 – 350 mOsm/Kg	300 – 350 mOsm/Kg	300 – 350 mOsm/Kg
Dynamic viscosity	25000 – 50000 mPa.s	50000 – 100000 mPa.s	100000 – 150000 mPa.s	150000 – 200000 mPa.s	200000 – 300000 mPa.s	> 400000 mPa.s
Molecular weight (Sodium Hyaluronate raw material)	2.5 x10 ⁶ - 3x10 ⁶ Da	2.5 x10 ⁶ - 3x10 ⁶ Da	2.5 x10 ⁶ - 3x10 ⁶ Da	2.5 x10 ⁶ - 3x10 ⁶ Da	2.5 x10 ⁶ - 3x10 ⁶ Da	2.5 x10 ⁶ - 3x10 ⁶ Da

Sede legale ed Operativa: Via Fratelli Bandiera – Nuovo Centro Commerciale – 80026 Casoria (NA)

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// Other Specifications

Reference Standard	Directive 93/42 CEE
Class	II a
Product Type	Medical device in compliance with the current legislation
Compatibility With Solutions	Sodium hyaluronate is incompatible with ammonium compounds Quaternary such as Benzalkonium Chloride solutions. Therefore, IalurOn®Bio pre-filled syringes should never come into contact with surgical instruments rinsed with these solutions or with ophthalmic products that contain quaternary ammonium compounds as preservatives.
Shelf Life and Sterilization Method	Product is valid for 2 years from the date of manufacture. Viscoelastic is steam sterilized in conformity to UNI EN ISO 17665, it must not be reused or resterilized. Cannula is sterilized with EtO in accordance with UNI EN ISO: 11135-1 / 2. The expiry date of kit is indicated on the packaging
Presence of Latex	No
Storage	Store at ambience condition, in dry place without humidity. Temperature must be in the range +2°C and +25°.
Information Reported on the Packaging	Batch number, expiry date, serial number, type of sterilization, manufacturer, CE mark.

