



PRODUKTKARTE

Hyaclean®

MEDICAL SODIUM HYALURONATE GEL

GTIN:

CE 2460

Hyaclean® (Medical sodium hyaluronate gel) is clear liquid gel, which is compounded sodium hyaluronate and physiological balancing salt. Hyaluronic Acid (herein after 'HA') is a unique type of linear macromolecular mucopolysaccharide, composed of repeating disaccharide units of glucuronic acid and N-acetylglucosamine, in chemical formula of $[C_{14}H_{21}NO_{11}]_n$. Hyaclean® is a high molecular weight (between 1.000,000-2.600,000) fraction of sodium hyaluronate (1.5% total weight) dissolved in a sodium phosphate buffer. The osmotic pressure of Hyaclean is nominally 270 mOsmol/kg~350mOsmol/kg.

Component

Hyaclean is processed with moist heat terminal sterilization. The product is for single use only. its final packaging includes one 27G blunt needle which is terminal sterilized by EO.

Ingredient	Sodium hyaluronate	NaCl	Na ₂ HPO ₄	NaH ₂ PO ₄	Water for injection
Content per mL	15mg	8.5mg	0.337mg	0.115mg	q.s.

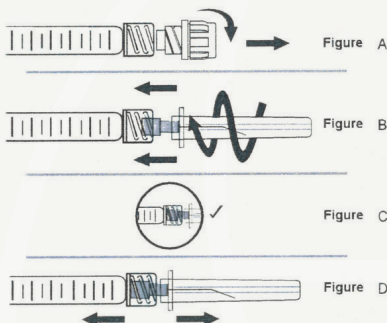


Figure1. Device installation steps

Indications

Hyaclean is intended to aid anterior or posterior segment ophthalmic surgery, including:

- Cataract extraction with/without implantation of intraocular lens;
- Corneal transplant surgery;
- Glaucoma filtering surgery;
- Secondary lens implantation.

Application

- Cataract surgery and IOL implantation

The required amount of Hyaclean is slowly infused through a needle or cannula into the anterior chamber. The protective effect of Hyaclean as an aid is optimized when the injection is performed prior to cataract extraction and insertion of the IOL and is effective for both intra- and extra-capsular procedures. Hyaclean may be applied to IOL prior to insertion. Additional Hyaclean can be injected as required to facilitate surgical procedures.

- Corneal transplant surgery

The corneal button is removed and the anterior chamber filled with Hyaclean is at level with the surface of the cornea. The donor graft is then placed on top of the Hyaclean and sutured into place. Additional Hyaclean can be used as required to aid in surgical procedures.

- Glaucoma filtration surgery

Hyaclean is injected through a corneal paracentesis to restore and maintain anterior chamber volume during the performance of the trabeculectomy. Additional Hyaclean can be used as required to aid in the surgical procedures.

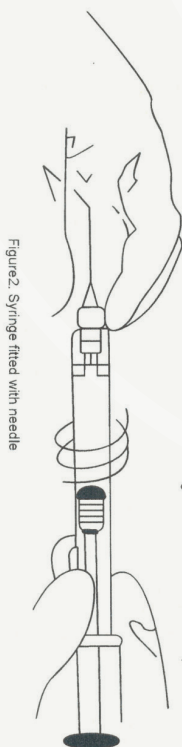


Figure2. Syringe fitted with needle