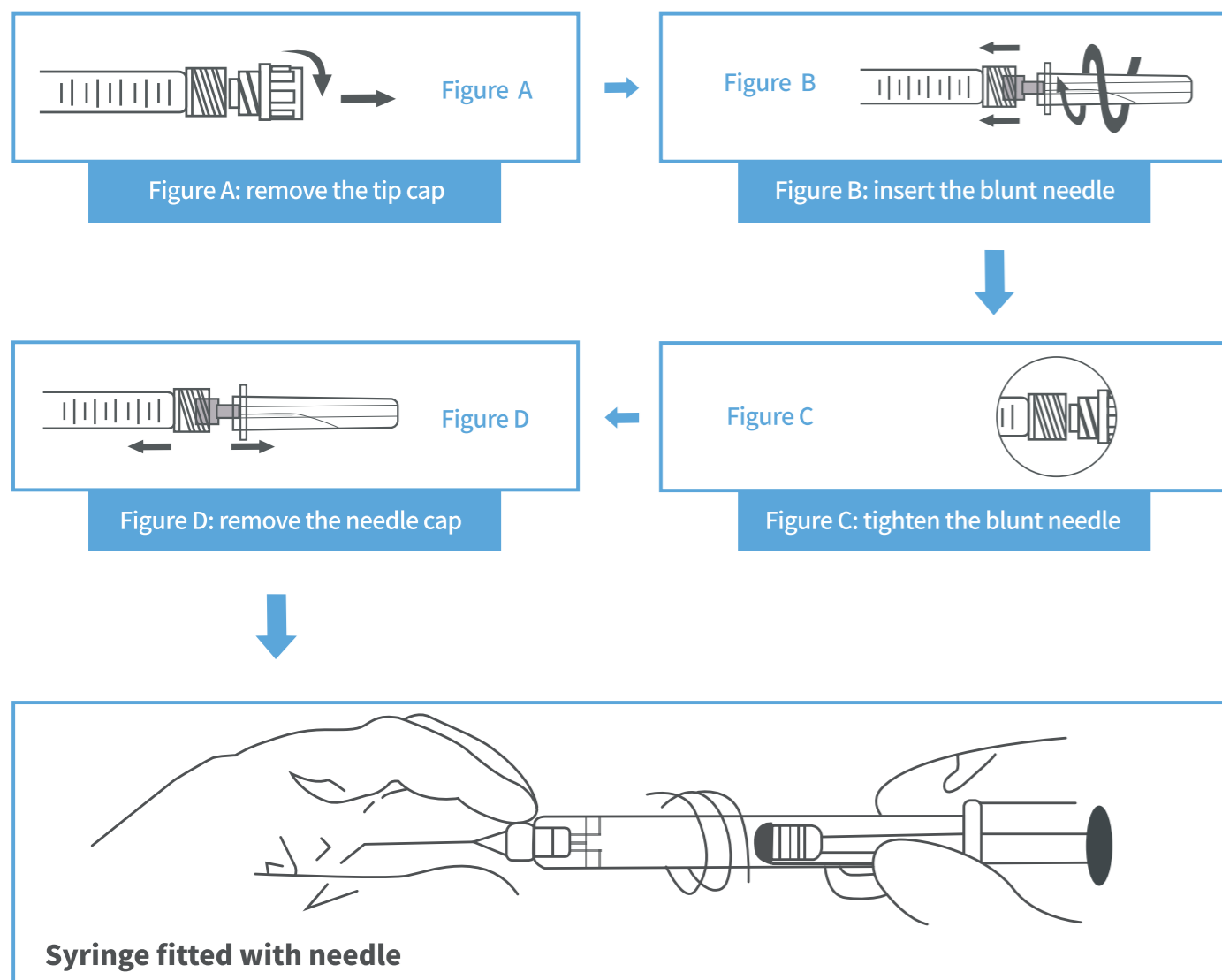


Installation Notes



Direction for use

- ▶ First expulse the air out of the ophthalmic Luer-lock needle, then inject Singclean® appropriately into eye. The injected amount must be adapted to the type of surgical procedures. The administration of Singclean® should be performed only by trained specialists.
- ▶ Over tightening may cause the hub to weaken and possibly detach from the syringe. Extrusion of a test droplet is recommended prior to entering eye, and excessive force on the plunger should be avoided.

SINGCLEAN

Singclean® Viscoelastic Solution for Ophthalmic Surgery

Product	Specification	Model No. Singclean®
Viscoelastic Solution for Ophthalmic Surgery	15 mg/mL: 0.5 mL	OPH-SC-15-0.5
	15 mg/mL: 0.75 mL	OPH-SC-15-0.75
	15 mg/mL: 1.0 mL	OPH-SC-15-1.0
	15 mg/mL: 2.0 mL	OPH-SC-15-2.0

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Powerful Space Creation and Maintenance

Singclean®

CE
2460

Viscoelastic Solution for Ophthalmic Surgery Medical Sodium Hyaluronate Gel

High Safety and Good Biocompatibility

Good Cohesion

High Viscoelasticity



Singclean®



Singclean® Viscoelastic Solution for Ophthalmic Surgery

Singclean® Medical sodium hyaluronate gel is a clear liquid gel, which is compounded sodium hyaluronate and physiological balancing salt.

Indication

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

- A Cataract extraction with/without implantation of intraocular lens
- B Corneal transplant surgery
- C Glaucoma filtering surgery
- D Secondary lens implantation

Model

15mg/mL: 0.5mL, 0.75mL, 1.0mL, 2.0mL.

Advantages

100% Non-animal Source & Good Biocompatibility

Raw material sodium hyaluronate comes from bacterial fermentation, no pyrogen, no rejection reaction, good biocompatibility, etc.

High Safety

Terminal sterilization / High cleanliness of the production environment / Using Germany Inova automated filling machine filling / High transparency of the products.

High Viscoelasticity

High molecular weight of 1,000,000~2,600,000 Daltons, shear viscosity $\geq 100,000$ mPa·s, which is conducive to the stable operation of repeated movement of surgical instruments during the surgical process and the reduction of mechanical damage in ultrasound.

Good cohesion

It can well maintain the depth of the anterior chamber.

Learn About Singclean® OVDs

OVDs were classified into two main groups, cohesive and dispersive, according to their rheological properties.

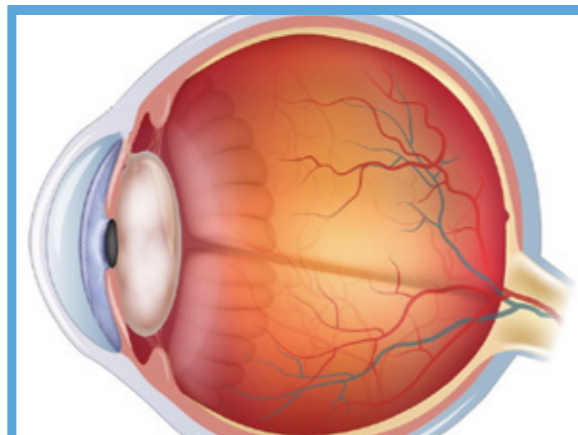
SINGCLEAN® OVD is Cohesive OVD

In the cataract surgery, the use of a cohesive OVD can help to enlarge a small and unresponsive pupil, to smooth the front capsule, and to create space by deepening the anterior chamber.



Literature Review

The frequency of intraocular pressure elevation at low concentrations of OVDs is less frequent than higher concentrations of OVDs. The concentration of SINGCLEAN is 15mg/mL, which is a low concentration.



“ The clinical effect of different concentrations of Ophthalmic viscoelastic devices on corneal edema during phacoemulsification cataract surgery: Group 1 brand H GV® (NaHA 14mg/ml), Group 2 brand V® (NaHA 30mg/ml-chondroitin sulfate 40mg/ml), Group 3 brand V® in phacoemulsification and brand P® (sodium hyaluronate 10mg/ml) intraocular lens implantation. We demonstrated that the transient increase in corneal thickness is more pronounced with brand H GV® than with brand V®, but brand H GV® is easier to clear, so the intraocular pressure change will be lower than brand V®.”
—Anders Behndig, Transient corneal edema after phacoemulsification: Comparison of 3 viscoelastic regimens[J] Cataract Refract Surg 2002; 28:1551-1556

Clinical Survey

Form 102 Clinical Surveys about the use of SINGCLEAN Viscoelastic Solution for Ophthalmic Surgery:

“All doctors made a positive comment on the product and most thought the treatment effect is excellent.”

post-market Surveillance



After SINGCLEAN was introduced to international markets in 2011, Post Market Data has been collected through a combination of active monitoring and passive collection. No adverse events and recalls have been received.



Global Sales Statistics

The total sales volume in the past five years totaled 1,424,421 pcs and it has been sold to over 33 countries and regions, which were sold to regions/countries mainly in China, Myanmar, Bolivia, Malaysia, the United Kingdom, South Africa, Germany, Belgium, etc. The sales figures for each country in the last 5 years are shown in the table below

Global Sales Statistics

