其胜®
QISHENG

Supply

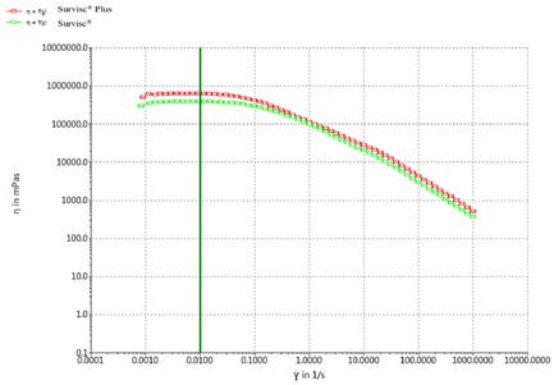
Trade	Concentration	Supply (each syringe)
Survisc®	15mg/ml	0.4ml/0.55ml/0.85ml/1.0ml
Survisc® Plus	20mg/ml	0.4ml/0.55ml/0.85ml/1.0ml

Survisc® and Survisc® Plus are collectively referred to as SURVISC

Description

SURVISC is a sterile, nonpyrogenic, non-inflammatory, transparent viscoelastic solution of highly purified sodium hyaluronate dissolved in buffered saline. Sodium hyaluronate is a naturally occurring linear glycosaminoglycan with a repeating disaccharide unit of sodium hyaluronate with a repeating disaccharide unit of sodium glucuronate and n-acetylglycosamine linked by a beta 1-3 glycosidic bond. SURVISC is a high molecular weight fraction of sodium hyaluronate (1.5%~2% total weight) dissolved in a sodium phosphate buffer (PH=6.8-7.6 at 25℃). The viscosity of different concentrations of SURVISC is different at shear rate of $0.01s^{-1}$, 25℃ (see graph 1). The osmolality of SURVISC is nominally 270mOsm/kg-350mOsm/kg.

Trade	Molecular weight	Viscosity
Survisc®	1,200,000 ~3,000,000	≥150,000mPa.s
Survisc® Plus	1,200,000~ 3,000,000	≥300,000mPa.s



Graph 1: Viscosity of SURVISC (shear rate of 0.01-100Hz , 25℃)

Component:

Ingredient	Contents	per ml
Trade	Survisc®	Survisc® Plus
Sodium hyaluronate	15mg	20mg
NaCl	8mg	8mg
Na_2HPO_4	0.5mg	0.5mg
$NaH_2PO_4.H_2O$	0.15mg	0.15mg
Water for injection	QS	QS

SURVISC is sterilized by moist heat. The filled syringes are sealed aseptically. EO-sterilized cannula is included with the product. We recommended that doctor can use 27 gauge cannula for inject the Survisc® and Survisc® Plus.

Indication:

SURVISC is indicated for using as a surgical aid in ophthalmic anterior segment surgery including cataract extraction, corneal transplant surgery, glaucoma filtering surgery and lens implantation.

Contraindications:

None known at present.

Precautions:

Precautions are limited to those normally associated with the surgery procedure being performed.

Overfilling the anterior segment of the eye with SURVISC may cause increased intraocular pressure, glaucoma, or other ocular damage.

Postoperative intraocular pressure may also be elevated as result of pre-existing glaucoma, compromised outflow and by operative procedure and sequelae thereto, including enzymatic zonulysis, absence of an iridectomy, trauma to filtration structures, and by blood and lenticular remnants in the anterior chamber.

Since the exact role of these factors is difficult to predict in any individual case. The following precautions are recommended:

- Injection by engaged in the professional medical staff.
- Don't overfill the eye chambers with SURVISC.
- Remove all remain SURVISC by irrigation and /or aspiration at the close of surgery.
- Carefully monitor the intraocular pressure especially the immediate postoperative period. If significant rises are observed, treat with appropriate therapy.
- SURVISC is obtained from microbial fermentation by a highly purified proprietary process. The physician should be aware of potential allergic risks that can occur with the injection of any biological material.
- Avoid reused of needle.
- Avoid trapping air bubble.
- On rare occasion, viscoelastic SURVISC containing sodium hyaluronate have been observed to become slightly opaque or to form a slight precipitated upon instillation into the eye. The clinical significance, if any, of this possibility, and, should it be observed, the cloudy or precipitated material should be removed by irrigation and/ or aspiration.
- Use only if material is clear.
- The product is for single use only. Reuse is prohibited. If the product reuse can result in bacterial infections, produce inflammation, and other infectious disease, or cause complications, or cause serious injury patients.

Adverse reactions:

SURVISC is extremely well tolerated after injection into human eyes.

A transient rise of intraocular pressure postoperatively has been reported in some cases.

Other adverse reactions have been reported following the use of SURVISC in intraocular surgery: corneal decompensation, endothelial damage, corneal oedema，striae and descemet' s folds, posterior capsular, and zonular rupture. The incidence of these adverse events is very low，and their relationship to SURVISC has not been established.

In the event of any serious adverse reaction , report it to the manufacturer, distributor, EU Representative or the competent authority.

Handling instructions:

SURVISC syringe must be taken out of the refrigerator approximately 20 minutes before use. After emptying the air out of the ophthalmic luer lock cannula, inject SURVISC appropriately into eye. The injection volume must be adapted to the type of surgical procedures.

Directions for use – syringe activation

1. Peel lid from blister pack under aseptic conditions.
2. Remove cap from syringe tip.
3. The cannula should be fastened with the syringe luer tip (shown in chart 1) ; however, over lightening may cause the hub to waken possible detach from the syringe. Extrusion of a test droplet is recommended prior to entering eye and excessive force on the plunger should be avoided.

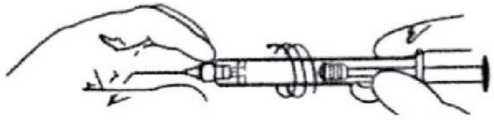


Chart 1: the needle fastened with the syringe

4. Gently push Syringe handle by hand, then make plunger rod to expel air bubbles from syringe tip and cannula.

Incompatibilities:

There is an incompatibility between sodium hyaluronate and solutions containing quaternary ammoniums, like benzalkonium chloride. It should then be avoided to let SURVISC in contact with medicochirurgical materials rinsed with such a solution or with ophthalmic topics containing a quaternary ammonium as a preserving agent.

Note:

- Check the integrity of the sterility individual protector before use. Do not use if sterile barrier is breached.
- Check the expiration date on the outer label before use
- For single-use

- Do not resterilize
- After the product is used, its packaging materials (syringes and cannulas) should be disposed of as medical waste.

Shelf life:

The shelf life of this product is 36 months.

Storage:

- Store between +2℃ to +8℃（+36℉to 46℉). It can be +2℃-+35℃(+36℉to 95℉)conditions of transportation. Transportation time under normal temperature shall not exceed one month.
- Protect from light and freezing
- Avoid shocks

Symbols used in the label

Symbol	Explanation
	Do not resterilize
	Do not reuse
	Sterilized using steam
	Sterilized using ethylene oxide
	Do not use if package is damaged and consult instructions for use
	Lot number
	Date of manufacture
	Use by (YYYY-MM-DD: year-month-day i.e. 2022-04-02)
	Store at 2℃ to 8℃
	Manufacturer
	Authorized representative in the European community
	Consult instructions for use
	Single sterile barrier system with protective packaging outside
	Caution
	Medical device
	Unique Device Identifier
	Keep away from sunlight
	Fragile, handle with care
	Keep dry
	CE mark

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