其胜 QISHENG

**Supply**

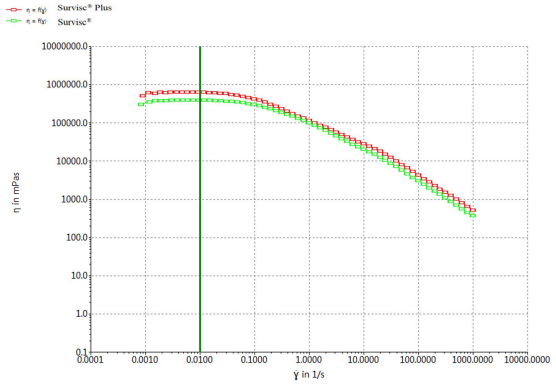
| Trade name | Concentration | Supply (each syringe) |
|---|---|---|
| Survisc® | 15mg/ml | 0.4ml/0.55ml/0.85ml/1.0ml |
| Survisc® Plus | 20mg/ml | 0.4ml/0.55ml/0.85ml/1.0ml |

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 name | 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℃)

**Clinical benefit:**

Clinical benefit: As an auxiliary tool in the whole ophthalmic surgery, it provides physical support to prevent damage to intraocular tissues.

**Life time:**

SURVISC would contact with eye, and the duration would not exceed 60 minutes.

**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. Inject this product only with the sterile single-use 27-gauge blunt needle provided in the product box. If the physician uses other 27-gauge cannula, it may result in an adverse event, such as scratching the patient's eye when using a sharp needle.

## Intended purpose:

SURVISC, a class of surgical invasive medical devices with viscous and/or viscoelastic properties, intended for use during surgery in the anterior segment of the human eye. SURVISC are designed to create and maintain space, to protect intraocular tissues and to manipulate tissues during surgery.

**Indication:**

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

**Target population:**

SURVISC is suitable for any adult patient with the above medical conditions, except pregnant/lactating women.

**Intended user:**

SURVISC should only be used by a surgeon who has received the training on ophthalmic surgery and who has a full understanding of the instructions and precautions. Before surgery, the operator should have a comprehensive understanding of the patient's medical history and medical condition.

**Contraindications:**

Avoid use in patients with known allergy to sodium hyaluronate

**Precautions:**

Intraocular pressure elevation after the use of sodium hyaluronate is a common complication following cataract or other eye surgeries.

Postoperative intraocular pressure may be elevated as a result of residual sodium hyaluronate in the eye and overfilling the anterior segment of the eye with sodium hyaluronate. Other conditions of pre-existing glaucoma and complications in surgical procedures (e.g. trauma to filtration structures, blood or residual cortex fragments in the anterior chamber) may also lead to increased intraocular pressure.

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

- Don't overfill the eye chambers with SURVISC.
- Remove all remaining SURVISC by irrigation and/or aspiration at the close of surgery.
- Carefully monitor the intraocular pressure especially during the immediate postoperative period. If significant IOP rises are observed, treat with appropriate therapy. For glaucoma patients, it is strongly recommended that extra care be taken to remove SURVISC from the eye and prophylactic pressure-lowering treatment should always be considered.
- SURVISC is obtained from microbial fermentation by a highly purified proprietary process. The surgeon should be aware of potential allergic risks that can occur with the injection of any biological material.
- Avoid reuse of needle.
- Avoid trapping air bubble.
- On rare occasion, viscoelastic SURVISC containing sodium hyaluronate may appear cloudy or form precipitates when it is injected. The surgeon should be aware of this phenomenon and, should it be observed, remove the cloudy or precipitated material by irrigation and/or aspiration.
- Use only if solution is clear.
- The product is for single use only. Reuse is prohibited. Product reuse can cause infections, inflammations, and even serious injuries.

**Adverse events:**

Intraocular pressure elevation has been reported after the use of SURVISC.

Intraocular pressure elevation is likely to occur if SURVISC is not removed as completely as possible. Clinical judgement concerning the use of this product should be considered in cases where thorough removal may not be possible. The Precautions noted above should be taken to prevent and manage postoperative intraocular pressure elevation.

Inflammation, conjunctival hyperemia, eye irritation, allergic reaction, corneal edema, endophthalmitis, hyphema, shallow anterior chamber, retinal detachment, macular edema, posterior capsule rupture, iris prolapse, iris injury, vitreous floaters, corneal disorder, posterior capsule opacification and cataract operation complication (glare) have also been recorded or reported after the use of SURVISC. The incidence of these adverse events is relatively low, and their relationship to sodium hyaluronate has not been established.

In the event of any serious adverse event, report 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 amount used varies with the type of surgery. The total amount introduced is usually less than1 ml in anterior segment surgery.

**Directions for use – syringe activation**

1. Peel lid from blister pack under aseptic conditions.
2. Remove cap from syringe tip.
3. Press the Luer-Lok adapter with hand. Grasp the cannula shield loosely with anther hand, mount the cannula on the Luer-Lok by turning it clockwise until you feel counter pressure (shown in chart 1).

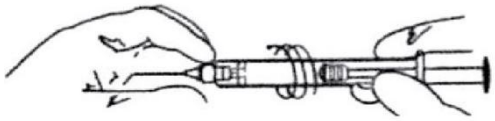


**Chart 1: the needle fastened with the syringe**

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 only
- Do not resterilize
- After the product is used, its packaging materials (syringes and cannulas) should be disposed of as medical waste.
- SURVISC is prefilled in a glass syringe, which may be damaged during transportation. To avoid injury to users or patients due to broken syringes during use, the syringe should be carefully checked for any abnormalities, such as cracks, deformation, or any other abnormalities, before use. If there are any abnormalities, please do not use.

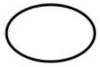
**Shelf life:**

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 |
|  | Consult instructions for use |
|  | Single sterile barrier system with protective packaging outside |
|  | Single sterile barrier system |
|  | Caution |
|  | Medical device |
|  | Unique Device Identifier |
|  | Keep away from sunlight |
|  | Fragile, handle with care |
|  | Keep dry |
|  | CE mark |


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