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Trypan Blue
Ophthalmic Solution

INSTRUCTION FOR USE

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INSTRUCTION FOR USE

- Risk of implantation: Ensure complete removal of Trypan Blue after staining is achieved by thorough cleaning with irrigating solution which removes the residual dye. The stained tissues removed from the eye may be treated as medical waste.
- Ensure safe and proper disposal of used/discarded product and packaging as per established procedure for handling biomedical waste

STORAGE

- Store in a cool, dry place
- Protect from light & freezing
- Expiry date showed on the pack indicates the period within which the device has to be used.

RETURN OF DAMAGED PRODUCT

Return the product in its original box identified by the LOT number, your purchase reference and reason for the return.

DISPOSAL OF DISCARDED PRODUCT AND PACKAGING

Ensure safe and proper disposal of used/discarded product and packaging to avoid adverse effect to environment, children and stray animals. The disposal should be incompliance to local laws related to disposal of biomedical waste, in the country ofuse.

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INSTRUCTION FOR USE

DESCRIPTION

Trypan blue Ophthalmic solution is used for intraocular use as a surgical aid during cataract and Vitreoretinal eye surgery. It is a blue dye that works by staining a part of the eye which creates a contrast between the different parts of the eye and helps the surgeon to see the different parts more clearly. It is a sterile, isotonic, solution and prepared by dissolving Trypan Blue powder in aqueous, isotonic solution. The pH range of the solution is maintained at 6.8 – 7.6.s

CLINICAL USE IN CATARACT SURGERY

During cataract surgery, it is used to stain the anterior capsule of the human lens. Inadequate visualization of the anterior capsule may result in improper or incomplete capsulorhexis, which carries a high risk of radial capsular tears and other associated complications. Staining of the capsule, improves its visualization and facilitates the performance of Capsulorhexis.

- It offers greatly enhanced visualization of the anterior capsule in eyes with mature cataract or narrow pupil.
- It provides a persistent and clear outline of the peripheral rim of the capsulorhexis by contrast between the stained rim and the adjacent lens mass.
- It reduces the risk of capsulorhexis-related complications by better visualization of radial capsule tears.
- It provides visualization of the "lost" edge of the capsulorhexis.

CLINICAL USE IN VITREORETINAL SURGERY

During retinal surgery, it is used to stain intraocular membranes, to visualize the Inner Limiting Membrane (ILM) and the External Limiting Membrane (ELM).

- It provides appropriate staining of the ILM with excellent visualization by virtue of clear outline of the ILM with visualization of the leading edge to facilitate complete rhexis removal of the ILM.

- It provides appropriate staining of the ERM with excellent visualization of transparent epi-retinal membranes.

CONTRAINDICATIONS

At present, there are no known contraindications, when used by a trained Surgeon,as recommended. However, care should be exercised for use in patients with hypersensitivity to any components of the solution

HOW SUPPLIED

The solution is supplied as sterile preparation aseptically filled in a prefilled syringe OR glass vial. The solution volume in the syringe/vial is 0.5-2 ml. The syringe /vial is placed inside a dry heat sealed pouch/blister. An angular cannula (22G or 23G), used for injecting the solution, is also supplied.

STERILIZATION

The solution is aseptically filled and sterilized by Moist Heat. The cannula supplied along with the ophthalmic solution is sterilized by Ethylene Oxide (EO). When placed in a blister pack, the outer surface of the ophthalmic solution container may be sterilized by Ethylene Oxide (EO).

INSTRUCTIONS FOR USE

- The Trypan Blue Solution is to be used by a qualified and trained ophthalmic surgeon only.
- It is supplied sterile in a vial (closed with a rubber stopper and aluminum flip off seal) or in a pre-filled syringe inside a heat sealed package.
- First, check the date of expiry on the box and make sure that the product is still valid.
- To remove the product, carefully peel open outer pouch/blister and remove the syringe/vial in sterile environment.
- If the product is supplied in a pre-filled syringe, attach the supplied cannula to the leur-lock of the syringe. Turn the cannula tightly in the lock so that no solution may leak while being instilled

Instruction For Use

- If the solution is in a vial then flip off the aluminum seal to expose the part of the rubber seal. Transfer the contents of the vial to a sterile syringe by puncturing the rubber seal with a sterile needle and aspirating the contents. And then affix a cannula to the syringe as mentioned.

PRECAUTIONS

- Trypan Blue solution is toxic in vitro to corneal endothelium and other ocular tissues at higher concentrations and notably longer exposure times. Though the concentration of the solution supplied is quite low, it is recommended that the solution should not be in contact with ocular tissues for a long time.
- It is recommended that after procedure, all excess Trypan Blue Solution be immediately removed from the eye through irrigation.
- Use of Trypan Blue is contraindicated when a non-hydrated (dry) hydrophilic intraocular lens (IOL) is to be implanted in the eye because the dye may be absorbed by the IOL and it may stain the IOL.
- Trypan Blue Solution should not be used in patients who show hypersensitivity to any of the components of the preparation.

WARNINGS

- The device is to be used by a qualified and trained ophthalmic surgeon only.
- The device is for intraocular use only.
- Do not use the package if the integrity of the sterile package is compromised.
- Do not use the solution if it has floating particles/crystals/sediments of any kind.
- The device is for single use only.
- Reuse of the device may result in inconsistent/inadequate staining of the ocular tissues and may cause of cross contamination and for transmission of bacteria and viruses
- Do not re-sterilize the device. Re-sterilization of the device will have a detrimental effect on its chemical properties thereby rendering it inappropriate for the use.

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