

Instructions For Use

Blue Eye (TS-905)

Submucosal Injection Agent



Blue Eye

The Blue Eye (TS-905), submucosal injection agent, is a solution used for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or endoscopic device in gastrointestinal endoscopic procedures. The main materials of the solution are sodium hyaluronate, Methylene Blue and normal saline, it is provided in prefilled syringe. It is supplied sterile and disposable.

INTENDED PATIENT

The Blue Eye (TS-905) for the patient who need to endoscopic procedures. The Blue Eye(TS-905) helps the patient who need to lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or endoscopic device.

INDICATION

The Blue Eye (TS-905) is intended for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or endoscopic device.

CONTRAINDICATION

Do not use for patients who are sensitive to any of the materials contained in Blue Eye

WARNINGS AND PRECAUTIONS

- The endoscopist injecting Blue Eye must be experienced Doctor in the administration technique.
- When inserting a needle into the intestine, the needle tip should be inserted diagonally (approx. 20° to 45°) right beneath the mucosa. If the needle tip is inserted vertically into the mucosa, there is a risk that it would penetrate the serosa.
- The maximum dosage is 50 mL per patient.
- The product compatibility with other substances has not been tested.
- The effects of Blue Eye sustain within 60 minutes.
- Products with opened syringe caps should be used immediately and Do not reuse the remainder.
- Do not use if the packaging (syringe) or the Luer-lock cap is damaged.
- Do not use if the solution is not clear, shows any signs of opalescence or contains floating or precipitated visible particles.
- Do not reuse Blue Eye after first opening. It can cause side effects like an inflammation, infection and etc.
- Do not inject Blue Eye into the blood vessels directly.
- Do not use for pregnant or lactating women or children under 18 years of age.
- Don't contact unspecified substances during use.
- Do not use this medical device with disinfectants containing quaternary ammonium salts (e.g., Benzalkonium chloride). This may cause a precipitate.

DOSAGE AND ADMINISTRATION

The Blue Eye can be injected through an endoscope via a normal, commercially available endoscopic injection needle (e.g.: a 2.3 mm x 230 cm endoscopic injection needle) having a needle diameter of 23 gauge (23G) or less (not provided with the device). The administered dose of Blue Eye should be determined based on the dimensions of the lesion to be removed. Inject into the submucosa the amount of Blue Eye needed to form a submucosal cushion of optimal height and shape for the lesion to be removed. During the procedure do not exceed a total dose of 50 mL per patient, either in single or in multiple administrations.

PREPARATION

- Endoscopic injection needle (23G recommended)
- Blue Eye

DIRECTIONS

- Take out the syringe from the container in the canister.
- Unscrew tip cap of the syringe.
- Expel the air from the syringe until some drops of the solution pour out of the tip.
- Securely screw the Luer-lock syringe directly to a suitable sterile the endoscopic injection needle.
- Fill the endoscopic injection needle with the Blue Eye solution and expel any air.
- Infuse a small quantity of the solution to determine the amount of force needed to inject the material.
- Retract the needle.
- Introduce the endoscopic injection needle through the working channel of the endoscope.
- Place the needle properly at the lesion to be excised and inject the needle diagonally (approx. 20° to 45 °) into the submucosa.
- Inject 1 to 2 mL into the injection site. (In this case, the lesion is raised to 3-10 mm.)
- When injected correctly, blue light appears immediately on the

injection site.

- Check for leaks when injecting, stop injection if there is leakage, and

carefully insert the needle into the submucosa.

- If necessary, inject the solution several times around the base of the lesion to sufficiently elevate it, and then polypectomy or endoscopic resection or dissection is performed.
- Dispose the empty or used syringes legitimately and store the unused syringes inside the container.

USES

The Blue Eye is a submucosal injectable composition to be used in endoscopic resection procedures in the upper and the lower gastrointestinal tract, such as the esophagus, the stomach, the intestine and the rectum. Blue Eye is injected into the submucosa, beneath the lesion to be excised.

The Blue Eye is designed to provide a submucosal cushion of optimal height and duration, allowing the endoscopist an easy and safe resection procedure: polypectomy, endoscopic mucosal resection (EMR), hybrid EMR and endoscopic submucosal dissection (ESD).

The Blue Eye does not require any special apparatus or equipment, and it is designed to be used with the most common endoscopic resection devices.

The solution has physicochemical properties suitable for injection in the target site via a normal, commercially available endoscopic injection needle (e.g.: a 2.3 mm x 230 cm endoscopic injection needle) having a needle diameter of 23 gauge (23G) or less (not provided with the device).

The syringes are supplied with a female Luer-lock closure, to be subsequently connected to the endoscopic injection needle with male Luer-lock connection fitting.

Following injection into the submucosa the Blue Eye reconfigures to occupy the interstitial space and forms a colored submucosal cushion of optimal height, that pushes the mucosa away from submucosal layer, allowing for an easy resection procedure.

The Blue Eye, as a colored clear solution, helps to clarify the area where it is injected, to assist the endoscopist in visualizing the margins of the target lesion and performing the resection procedure, thereby decreasing the risk of damaging the external muscular layer, which could lead to perforation.

STORAGE

Store at room temperature.

Protect from light. Do not freeze.

Do not use if packaging is damaged.

Sterile product for single use only.

Do not use after expiry date.

Shelf life is 2 years

SYMBOLS



Manufacturer



Date of Manufacturer



Used by



Batch code



Catalogue number



Non-pyrogenic



Caution



Do not Reuse



Prescription Only



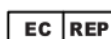
Steam Sterilization



Single Sterile Barrier



Do not use if package is damaged



EC representative



Medical Device



Unique device identifier



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