



INSTRUCTIONS FOR USE- Black Eye

The Black Eye is an endoscopic marker used for marking lesions in the GI tract. The marker ink is contained in 5ml/1ml syringe. It is supplied sterile and disposable. The composition of Black Eye is as follows: water, glycerol, carbon black.

Indication for use

The Black Eye (TS-205 & TS-201) is indicated for endoscopically marking lesions in the GI tract when the endoscopist anticipates the lesion will require surgical removal within 30 days.

Contraindications

The Black Eye is contraindicated in patients with a known hyper-sensitivity to any of the ingredients in the product.

Complications

- Leakage from the puncture site
- Abdominal abscesses
- Focal peritonitis and staining
- Transmural injection to small bowel
- Pigmentation peritonealadenocarcinoma(tumorinoculation)
- Infected intramural hematoma and abscess
- Rectus muscle hematoma and abscess
- Spillage of dye into peritoneal cavity
- Idiopathic inflammatory bowel
- Inflammatory pseudotumors
- Post operation adhesion

Warning and precautions

- Do not use when the package is open or damaged.
- The injection needle should not be inserted perpendicular to the colon wall directly not to penetrate the serosa.
- Do not reuse Black Eye after first opening. It can cause side effects such as inflammation, infection and etc.
- Do not inject Black Eye into the blood vessels directly.
- Do not use for pregnant or lactating women or children under 18 years of age.
- Do not contact unspecified substances during use.
- The endoscopist injecting Black Eye must be experienced Doctor in the administration technique.
- Discard any unused product after the syringe has been opened.
- After use, the product may have a potential biohazard. Handle and dispose of in accordance with hospital, local, and administrative laws and regulations.

Direction for use

1. Preparation: Black Eye, Endoscope, Injection needle. A 23-25gauge sclerotherapy needle with a needle length of 4 mm or less is recommended for this procedure.
2. Unfasten the cap of the Black Eye.
3. Attach the syringe to the luer fitting on the Injection needle.
4. Insert the Injection needle through the biopsy channel of the endoscope. When the needle is properly positioned, insert the tip 30°-45° tangentially into the submucosal space of the colon.
CAUTION: Do not insert the needle perpendicular to the colon as this may lead to perforation of the serosa and injection of the marker directly into the peritoneal cavity!
5. Inject 0.5-0.75 ml of the marker into each injection site. This volume typically produces a mark on the colon measuring 1-2 cm in diameter. When properly placed there is an immediate black blush of the marker at the injection site.
6. Observe for leakage of the marker into the colon lumen. If this occurs, stop the injection and cautiously insert the needle further into the submucosa. A minimum of four marker injections is recommended, one in each of the four quadrants of the colon around the area of the lesion. This technique assures that at least one of the marks can be observed by the operating surgeon from the serosal side of the colon and, if another endoscopy is necessary, the lesion can be observed from inside the lumen as well. The maximum recommended dose is 8 ml per patient.

Storage and Shelf life

Store the product at room temperature. Shelf life is 2 years.

SYMBOLS



Lot Number



Catalog number



Use by



Date of manufacture



Manufacturer



Do not re-use



Steam sterilization



Caution



Do not use if package is damaged

Rx Only Prescription only

Made in Korea.

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