



Blue Beacon™ GI Marker 0.8% Vial Instructions for Use



IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech.

Main Components

Indigo-5, 5'-Disulfonate, Sodium Pyrosulfite, Water for Injection

INTENDED USE

Blue Beacon™ GI Marker, Indigo Carmine 0.8% is indicated for temporary endoscopic marking of tissue in the GI tract, to aid tissue visualization.

CONTRAINDICATIONS

- Gastrointestinal obstruction or perforation;
- Allergy to device or any of the ingredients in the product.

POTENTIAL COMPLICATIONS

No adverse effects or patient discomfort were reported with Blue Beacon™ GI Marker. However, any inadvertent injection of marker into the intraperitoneal space should be monitored closely for adverse reactions.

WARNINGS

- For use in the GI tract only– NOT FOR INTRAVASCULAR OR INTRAMUSCULAR INJECTION.
- Only the fluid is sterile. Do not use in a sterile or aseptic area without proper precautions.
- Product MUST BE DILUTED with at least 10ml of sterile water for injection before use. Product concentration should be 0.4% or less.
- **The product is intended for single patient use only! DO NOT re-use, re-sterilize, and/or reprocess.** Re-use, re-sterilization or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, re-sterilization or reprocessing may also create a risk of contamination of the device and/ or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, re-sterilized or reprocessed.
- Do not use this instrument for any purpose other than its intended use.
- The product is only intended for adult populations.
- This device is not made with natural rubber latex.
- **The instrument is intended for use under the direct supervision of a trained physician only.** A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.

【Product Name】 Blue Beacon™ GI Marker

【Concentration】 Indigo Carmine: 0.8% +/- 0.1%, dilute before using

【Packaging】 Packaged in vial inside a sealed pouch

【Production Date】 See packaging

【Sterilization】 Fluid sterilized by steam

【Shelf Life】 2 years

PREPARATION

1. Reference the product label and choose the appropriate device.
2. Fluid is supplied STERILE.
3. Open the package carefully after verifying the expiration date.
CAUTION: For use in the GI tract only–NOT FOR INTRAVASCULAR OR INTRAMUSCULAR INJECTION
4. Sterile unless damaged. Leakage of product maybe evidence of damage. Do not use if damaged.
5. Dilute the solution with at least 10mLs of sterile water for injection to achieve 0.4% or less indigo carmine concentration prior to clinical use.

INSTRUCTIONS FOR USE

1. Select a suitable endoscopic injection needle or spray catheter, with a luer lock connection. Prime the catheter prior to use.
2. With the needle retracted, carefully insert the catheter through the biopsy channel of the endoscope under direct visualization until the needle emerges into the endoscopic view.
3. When the needle is properly positioned, advance the needle and inject into the target tissue.

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!

4. Carefully inject aliquots as directed by the physician.

CAUTION: Observe for leakage of the marker into the lumen. If this occurs, stop the injection and reposition the needle.

STORAGE

The product should be stored in the dark, at room temperature.

PRODUCT DISPOSAL

1. Discard any unused product after the vial has been opened.
2. After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local, and administrative laws and regulations.

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