



insert the catheter through the biopsy working channel of the endoscope.

When the needle is properly positioned, insert the tip 30°–45° tangentially into the submucosal space of the GI wall. **CAUTION: Do not insert the needle perpendicular to the GI wall, as this may lead to perforation of the serosa and injection of the tattoo suspension directly into the peritoneal cavity!**

Inject 0.5–0.7 mL of the tattoo into each injection site. This volume typically produces a mark on the GI wall measuring 1–2 cm in diameter. When properly placed, there is an immediate black blush of the tattoo at the injection site. Observe for leakage of the tattoo into the lumen. If this occurs, stop the injection and cautiously insert the needle further into the submucosa. Consider using the saline test bleed method, which first injects 1 mL of saline to create a mound or bleb prior to injecting Spot Ex. The saline test bleed method confirms placement in the submucosal layer. Each steam sterilized, non-pyrogenic syringe contains 5 mL of the following ingredients:

- Water
- Benzyl Alcohol △
- Polysorbate 80
- Simethicone
- Glycerol
- High-purity Carbon Black

Spot® Ex Endoscopic Tattoo INSTRUCTIONS FOR USE

DESCRIPTION

Spot® Ex Endoscopic Tattoo (Spot Ex) is a specially formulated, biocompatible suspension designed for endoscopically tattooing or marking lesions in the gastrointestinal (GI) tract. The suspension contains highly purified, very fine carbon particles which remain in the submucosal injection site creating a permanent tattoo. Each steam sterilized, non-pyrogenic syringe contains 5 mL of the following ingredients:

- Water
- Benzyl Alcohol △
- Polysorbate 80
- Simethicone
- Glycerol
- High-purity Carbon Black

INDICATION FOR USE

Spot Ex is indicated for endoscopically tattooing lesions in the GI tract for up to 36 months to facilitate clinical surveillance or surgical localization.

CONTRAINDICATIONS

Spot Ex is contraindicated in patients with a known hypersensitivity to any of the ingredients in the product. **Not for pediatric use**

WARNING AND PRECAUTIONS

Some settling of the carbon pigment is normal. The syringe should be shaken vigorously for 15–20 seconds prior to loading the injection needle.

Spot Ex is a single-patient-use product. It is sterile unless damaged. Leakage of product may be evidence of damage. Do not use if damaged. Discard any unused product after the syringe has been opened. To avoid cross-contamination, each syringe may only be used on one patient and cannot be reused. The suspension may stain clothing or porous materials.

When using an injection needle in the GI tract, the needle should be inserted into the GI wall at an angle so that the beveled tip of the needle is entirely beneath the mucosa. If the needle is inserted perpendicular to the mucosa, there is a risk of penetrating the serosa and injecting the tattoo suspension directly into the peritoneal cavity.

SIDE EFFECTS

Any inadvertent injection of tattoo suspension into the intraperitoneal space should be monitored closely for adverse reactions.

DIRECTIONS FOR USE

IMPORTANT: The Spot Ex syringe should be shaken vigorously for 15–20 seconds prior to loading the injection needle.

Examine the syringe to verify that the pigment is fully suspended. Then, using aseptic technique, attach the syringe to the luer fitting on the needle. A 23 or 25-gauge injection needle, with a needle length of 4 mm or less, is recommended for this procedure. **Prime the needle with Spot Ex prior to injection.** With the needle retracted,

insert the catheter through the biopsy working channel of the endoscope.

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STORAGE AND SHELF LIFE

Store the product at room temperature. The product has a shelf life of two years. The expiration date and the lot number are printed on the syringe label. Store the syringe with the syringe tip pointing upward or luer on its side.

Do not store with the syringe tip pointing down. Storing the syringe tip down may allow a portion of the carbon pigment to settle into the narrow syringe outlet and prevent it from being re-suspended.

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CUSTOMER SERVICE

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Spot® is a registered trademark of GI Supply.

This Spot® Ex Endoscopic Tattoo product is covered by the following U.S. patent numbers: U.S. Pat. No. 6,280,702 and U.S. Pat. No. 6,599,496.

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