



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 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**
- **Polysorbate 80**
- **Glycerol**
- **Benzyl Alcohol** ⚠
- **Simethicone**
- **High-purity Carbon Black**

INDICATION FOR USE

Spot[®] Ex is indicated for endoscopically tattooing lesions in the GI tract permanently 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 colon, the needle should be inserted into the colon 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.

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 tattoo suspension directly into the peritoneal cavity!**

Inject 0.5–0.75 mL of the tattoo 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 tattoo at the injection site. Observe for leakage of the tattoo into the colon lumen. If this occurs, stop the injection and cautiously insert the needle further into the submucosa. Consider using the saline test bleb method, which first injects 1 mL of saline to create a mound or bleb prior to injecting Spot® Ex. The saline test bleb method confirms placement in the submucosal layer.

Three to four tattoo injections are recommended to create a circumferential pattern around the lesion. This technique assures that at least one of the marks can be observed during surgery from the serosal side of the colon or during endoscopic surveillance.

The maximum recommended dose is 8 mL per patient.

After use, properly dispose the product in the appropriate medical device waste container.

STORAGE AND SHELF LIFE

Store the product at room temperature (20° to 25°C). 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 pointed upward or lying 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.



Sterile Fluid Path

RxOnly

Caution: Federal law restricts this device to sale by or on the order of a physician.



Use by Date
(Expiration Date)



Lower Limit Temperature



Lot Number



Keep Dry



Consult Instructions
for Use (IFU)



Manufactured by



Caution



Do Not Use If
Package Is Damaged



Non-pyrogenic

CUSTOMER SERVICE



GI Supply • 200 Grandview Ave., Camp Hill, PA 17011 USA •
800.451.5797 • 8:30 a.m. to 5 p.m. EST,
Monday–Friday • www.gi-supply.com
orders@gi-supply.com

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.