**Spot®**

**Description**
SPOT is a specially formulated, biocompatible agent designed for endoscopically parking or "tagging" lesions in the GI tract. SPOT is a suspension containing highly purified, very fine carbon particles. The particles remain in the submucosal injection site creating a permanent mark. Each steam sterilized, non-pyrogenic syringe contains 5 cc of the marker.

**Composition**
- Water for injection
- Glycerol
- Polysorbate 80
- Benzyl Alcohol
- Simethicone
- High Purity Carbon Black

**Indication for use**
SPOT is indicated for endoscopically marking lesions (such as colon cancer and polyps) in the GI tract when the endoscopist anticipates the lesion will require surgical removal within 30 days.

**Contraindications**
Spot is contraindicated in patients with a known hypersensitivity to any of the ingredients in the product.

**Warning and precautions**
Some settling of the carbon pigment is normal. The syringe should be shaken vigorously prior to loading the injection needle.
Spot is a sterile single-use only product. Sterile unless damaged. Leakage of product may be evidence of damage. Do not use. Discard any unused product alter the syringe has been opened. To avoid cross contamination each syringe can only be used on one patient and cannot be reused. Although the material is non-toxic, the marker may stain clothing or porous materials.
When using a sclerotherapy 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 marker directly into the peritoneal cavity.

**Side Effects**
During the clinical study, no adverse effects or patient discomfort were reported with SPOT. However, any inadvertent injection of marker into intraperitoneal space should be monitored closely for adverse reactions.

**Directions for use**
A 25 gauge sclerotherapy needle with a needle length of 4 mm or less is recommended for this procedure. IMPORTANT: The SPOT syringe to verify that the pigment is fully suspended. Then attach the syringe to the luer fitting on the needle. With the needle retracted, insert the catheter 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!

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.
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. The product has a shelf life of two years. The expiration date and the lot number are printed on the syringe label. Store the syringes in the canister provided with the syringe tips pointed upward.
Do not store with the syringe tips pointing down. Storing the syringes with tips down may allow a portion of the pigment to settle into the narrow syringe outlet and prevent the pigment from being re-suspended.

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Endoscopic marking of colon lesions.

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