

# EverLift™

## Submucosal Lifting Agent

### INSTRUCTIONS FOR USE

#### DESCRIPTION

EverLift submucosal lifting agent is a sterile, blue-colored emulsion to be used in endoscopic resection procedures during endoscopic examinations in the upper and the lower gastrointestinal tract, such as the esophagus, the stomach, the intestine, and the rectum, designed to elevate the mucosal layer and the tissue to be excised from the submucosal and the external muscular layer.

#### COMPOSITION

Each steam sterilized syringe contains 5mL of lifting agent with the following ingredients:

- Water
- Hydroxyethyl Cellulose
- Sodium Phosphate
- Glycerin
- Methylene Blue
- Benzyl Alcohol ⚠
- Potassium Phosphate

#### INDICATION FOR USE

EverLift Submucosal Lifting Agent is indicated for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers, or other gastrointestinal lesions prior to excision with a snare or other appropriate endoscopic device.

#### CONTRAINDICATIONS

EverLift is contraindicated in patients with a known hypersensitivity to any of the ingredients in the product.

⚠ **Not for pediatric use.**

⚠ **Not for use in pregnant or lactating women.**

#### ⚠ WARNINGS AND PRECAUTIONS

The endoscopist, nurse, or endoscopy technician injecting EverLift must be experienced in submucosal injection techniques.

EverLift 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.

#### SIDE EFFECTS

Any inadvertent injection of lifting agent into the peritoneal cavity should be monitored closely for adverse reactions.

#### DIRECTIONS FOR USE

Remove the cap from the tube and remove the syringe.

Examine the syringe to verify that there is no damage. Then, using aseptic technique, attach the syringe to the luer fitting on the needle. A 23-gauge endoscopic injection needle with a needle length of 4 mm or less is recommended for this procedure. Prime the needle with EverLift prior to injection. With the needle retracted, insert the needle's catheter through the working channel of the endoscope.

When the needle is properly positioned, insert the tip at a 30°–45° angle to the surface into the submucosal space of the gastrointestinal tract, ensuring the tip of the needle is entirely beneath the mucosa.

⚠ **CAUTION:** *Do not insert the needle perpendicular to the colon surface, as this may lead to transmural injection of the lifting agent directly into the peritoneal cavity.*

Observe for leakage of the lifting agent into the colon lumen. If this occurs, stop the injection and cautiously insert the needle further into the submucosa.

The maximum allowable dose is 50 mL per patient.

Draw back slightly on the plunger rod upon completion of injection and prior to withdrawing the needle from the submucosal space to prevent leakage of formulation into the colon lumen caused by pressure build-up.















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

#### STORAGE AND SHELF LIFE


Store the product at room temperature (15–30°C). Store in a dark place.

The expiration date and the lot number are printed on the syringe label.

#### DESCRIPTIONS OF SYMBOLS

	Sterile Fluid Path Sterilized Using Steam or Dry Heat		Temperature Limit
	Consult Instructions for Use (IFU)		Keep Dry
	Caution		Do Not Use if Package is Damaged
	Non-Pyrogenic		Do Not Re-Use
	Keep Away From Sunlight		Batch Code
	Use-By Date		Catalog Number
	Manufactured By		Caution: Federal law restricts this device to sale by or on the order of a physician.

#### CUSTOMER SERVICE

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