Laborie

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GI

EverLift®

Submucosal Lifting Agent FAQ

GASTROENTEROLOGY

Reliable Life
Cost Effective
Conveniently Packaged

EverLift®
Submucosal Lifting Agent

What is EverLift?

EverLift is a colored (blue), sterile, clear emulsion that is a liquid injectable. EverLift is intended for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early stage cancers or other gastrointestinal mucosal lesions, prior to removal with a snare or endoscopic device. It facilitates 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.

How does EverLift work and for how long will it lift?

EverLift is designed to elevate the mucosal layer and the tissue to be excised from the submucosal and the muscular layer, thereby allowing an easy and safe endoscopic mucosal resection (EMR), hybrid EMR, and endoscopic submucosal dissection (ESD). EverLift holds a 2 mm lift for 60 minutes as demonstrated in benchtop ex-vivo testing.

What is contained within EverLift?

The emulsion consists of the following:

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

Why does EverLift contain Methylene Blue?

EverLift's blue color comes from Methylene Blue which helps in visualizing the lesion and performing the resection procedure, thereby helping to minimize the risk of perforation. In addition, the staining of the submucosal layer will help facilitate the identification of muscle injury.

What is the procedure for the preparation of EverLift for injection?

Preparation of EverLift for injection is as follows:

- Remove the cap from the tube and remove the syringe.
- Examine the syringe to verify there is no damage.
- Using aseptic technique, attach the syringe to the luer fitting on the endoscopic injection needle (not provided).
- Prime the needle with EverLift prior to injection.
- With the needle retracted, insert the needle's catheter through the working channel of the scope.

Where is EverLift injected and how much do you inject?

Insert the tip of the injection needle 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. The maximum allowable dose is 50 mL per patient.

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.

Can I reuse an opened syringe of EverLift® on another patient?

No. EverLift is provided in syringes for single use only. Any product in an opened syringe, that was not injected, should not be used for another patient.

What size needle can EverLift pass through?

A 23-gauge endoscopic injection needle with a needle length of 4 mm or less is recommended for this procedure.

Are there any studies looking at the efficacy of EverLift?

Extensive pre-clinical animal testing was conducted in support of the FDA submission and 510(k) clearance of EverLift. Ex-vivo benchtop testing was also conducted and shows EverLift will hold a 2 mm lift for 60 minutes.

Does EverLift produce artifacts in pathology post EMR/ESD?

Laborie's 2021 post-market clinical follow-up study of its 5 mL and 10 mL syringes validated that EverLift Submucosal Lifting Agent does not produce artifacts.

Read the whitepaper by scanning the QR code.

What adverse events have been observed with EverLift and what are the contraindications?

Rarely, local bleeding and/or inflammatory reaction could occur which may or may not be associated with EverLift. The contraindications for EverLift are:

- Patients with any known hypersensitivity to any of the ingredients in the product.
- Not for pediatric use.
- Not for use in pregnant or lactating women.

Are there any warnings and precautions I should know about?

- The endoscopist, nurse or endoscopy technician injecting EverLift must be experienced in submucosal injection techniques.
- EverLift is a single patient use product. To avoid cross-contamination, each syringe can only be used on one patient and cannot be reused. Discard any unused product after the syringe has been opened.
- It is sterile unless damaged. Do not use if damaged. Leakage of product may be evidence of damage.
- Do not use if the emulsion shows any signs of opalescence or contains floating or precipitated visible particles.
- The product compatibility with other substances has not been tested.

Does EverLift interact with other drugs?

The interaction of EverLift with other drugs has not been tested.

How can I report a device-related adverse event or product complaint related to EverLift?

Please call our toll-free customer service number at 800-522-6743 or reach out to your local Laborie sales representative.

How is EverLift packaged and supplied?

EverLift is available in both 5 mL and 10 mL syringes and is sold in a box of 10. It is packaged in individual, pre-filled tubes, and connects to any universal luer lock connection on an endoscopic injection needle.

How do I store EverLift and what is the expiration date?

EverLift should be protected from light and stored at room temperature between 15°C and 30°C. For the expiration date, see the shipper box, shelf box, tube or individual syringe. Currently, the expiration date is two years after the date of manufacture.

How can I order EverLift or obtain additional medical information?

- Call: (800) 522-6743 (8:30am-5:00pm EST Monday – Friday)
- E-mail: gis-gisupplyinfo@laborie.com
- Fax: (717) 761-0216
- or visit laborie.com/everlift

Who developed and manufactures EverLift?

EverLift was developed by GI Supply. GI Supply has been the manufacturer of the Global Endoscopic Tattoo, Spot, for over 20 years.

Why is EverLift classified by the FDA as a medical device and not as a drug?

The FDA regulates medical products as drugs or devices, when they are intended to cure, treat, mitigate, diagnose, or prevent disease in humans, or affect the structure or function of the human body. A regulated medical product is classified as a drug if it achieves its primary intended purposes through chemical action within or on the human body. The primary intended purpose of EverLift is submucosal lift, which is a mechanical action. EverLift does not achieve this primary intended purpose through chemical action within or on the body and is not dependent on being metabolized for the achievement of its primary intended purposes. Therefore, the FDA classifies EverLift as a medical device. More explanation, including the FDA statutory definitions of drug and device, may be found in the FDA draft guidance document, Classification of Products as Drugs and Devices (September 2017), available at https://www.fda.gov/media/80384/download

What is the barcode/GTIN (UDI) number for EverLift?

The following are the GTIN (UDI) numbers for EverLift:

PACKAGE LEVEL	DESCRIPTION	GTIN
Base Unit (Syringe)	Individual syringe packaged in a tube 5 mL	00893029002229
Case (Box)	EverLift® Submucosal Lifting Agent 5 mL	10893029002226
Base Unit (Syringe)	Individual syringe packaged in a tray, 10 mL	00893029002243
Case (Box)	EverLift® Submucosal Lifting Agent 10 mL	10893029002240

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