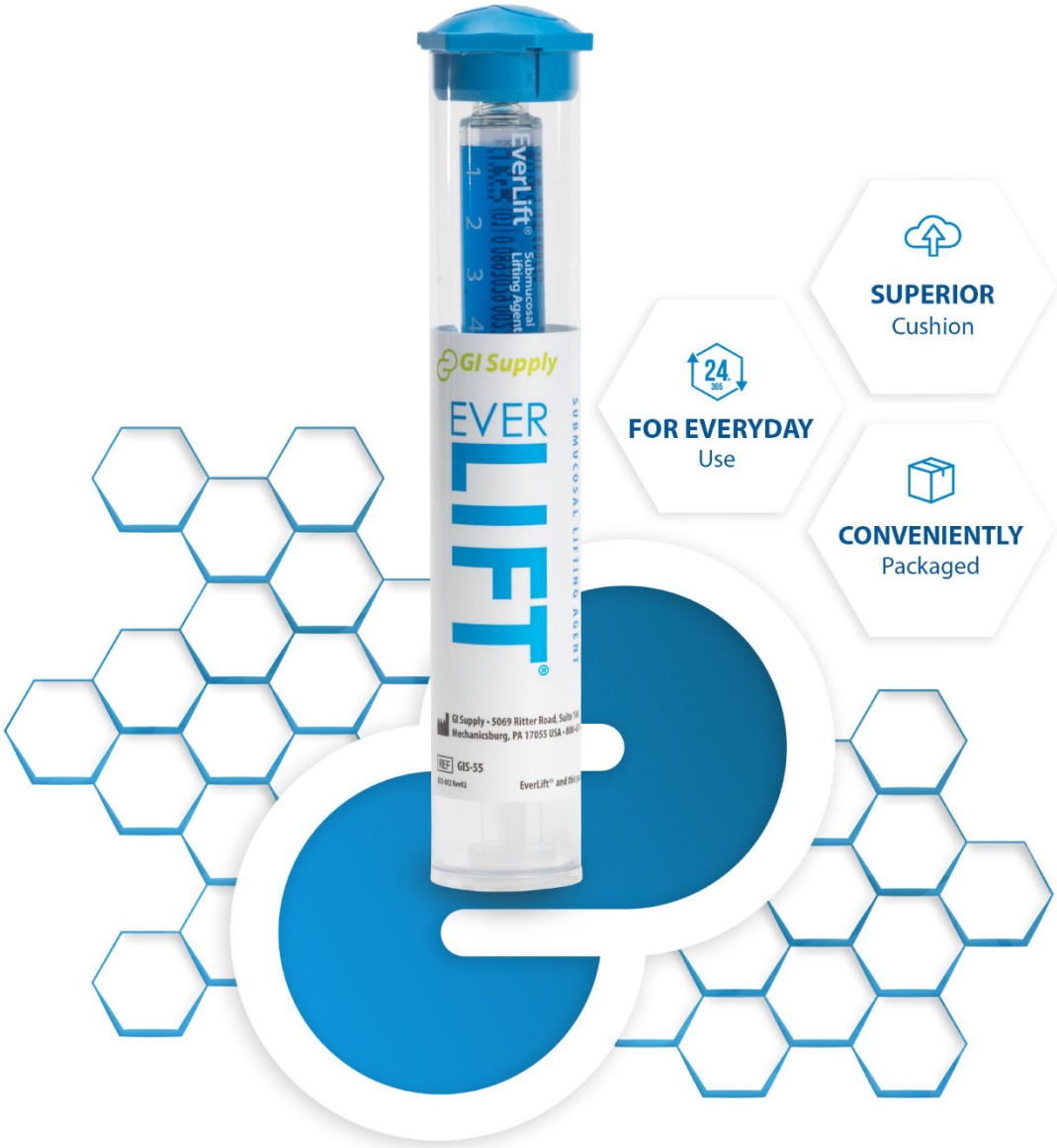
GI Supply
Specialty Endoscopic Products



EverLift®
Submucosal Lifting Agent

Frequently Asked Questions

ENDOMED PTY. LTD.
SPECIALISING IN ENDOSCOPY
A.B.N. 98 050 413 379

ENDOMED PTY. LTD.
POST OFFICE BOX 445,
STRATHPINE QLD. 4500

orders@endomed.com.au

TELEPHONE 07 3881 1883
1800 773 474
FACSIMILE 07 3881 0211

1. What is EverLift®?

EverLift® submucosal lifting agent is a sterile, blue-colored emulsion. 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.

2. 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, away from the submucosal and the muscular layer, thereby facilitating an endoscopic mucosal resection (EMR), hybrid EMR or endoscopic submucosal dissection (ESD). EverLift® sustains a 2 mm lift for 60 minutes as demonstrated in benchtop ex-vivo testing.[1]

3. What are the ingredients in EverLift®?

The emulsion consists of the following:

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

4. Why does EverLift® contain Methylene Blue?

EverLift® contains methylene blue because it helps in visualizing the lesion and performing the resection procedure, thereby helping to minimize the risk of perforation. In addition, the staining of submucosal layer will help facilitate the identification of muscle injury.

5. What is the procedure for the preparation of EverLift® for injection?

a) Remove the cap from the tube and remove the syringe.

b) Examine the syringe to verify there is no damage.

c) Using aseptic technique, attach the syringe to the Luer fitting on the endoscopic injection needle (not provided).

d) Prime the needle with EverLift® prior to injection.

e) With the needle retracted, insert the needle's catheter through the working channel of the endoscope.

f) When 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.

6. Where is EverLift® injected and how much do you inject?

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.

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

No. EverLift® is for single-patient use only. 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.

8. What size needle can EverLift® pass through?

A 22 or 23-gauge endoscopic injection needle with a needle length of 4 mm or less is recommended.

9. Are there any studies reviewing the efficacy of EverLift®?

Extensive pre-clinical animal testing and ex-vivo bench top testing was conducted and shows EverLift® will hold a 2 mm lift for 60 minutes.[1]

1. Data on file

ENDOMED PTY. LTD.
SPECIALISING IN ENDOSCOPY
A.B.N. 98 050 413 379

ENDOMED PTY. LTD.
POST OFFICE BOX 445,
STRATHPINE QLD. 4500

orders@endomed.com.au

TELEPHONE 07 3881 1883
1800 773 474
FACSIMILE 07 3881 0211

10. What adverse events could be observed with EverLift® and what are the contraindications?

Rarely, local bleeding and/or an 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.

11. 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 by 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.
- The product compatibility with other substances has not been tested.

12. Does EverLift® interact with other drugs?

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

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

Contact your local GI Supply distributor: *www.gi-supply.com/global-distributors/locations/*

14. Does EverLift® require any special apparatus or equipment?

EverLift® does not require any special apparatus or equipment, and it is designed to be used with the most common endoscopic resection devices. EverLift® can be injected through an endoscope via a normal, commercially available 22 or 23 gauge (23G) endoscopic injection needle (not provided with the device).

15. How is EverLift® packaged and supplied?

EverLift® is sold as a 10-syringe box. EverLift® comes in a syringe with a universal Luer connection that will connect to any normal, commercially available 23 gauge (23G) endoscopic injection needle. Each syringe contains either 5 mL or 10 mL of product and is packaged in an individual tube.

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

EverLift® should be protected from light and stored at room temperature (15°C and 30°C). Store in a dark place. To locate 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.

17. How can I order EverLift® or obtain additional medical information?

Contact your local GI Supply distributor: *www.gi-supply.com/global-distributors/locations/*

18. Who developed and manufactures EverLift®?

EverLift® was developed by GI Supply. GI Supply is the #1 Global Leader in endoscopic tattooing with the product Spot® Ex. GI Supply is physician founded and manufactures in the US at its facility located in Mechanicsburg, PA.

19. Why is EverLift® classified by FDA as a medical device and not as a drug?

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

ENDOMED PTY. LTD.
SPECIALISING IN ENDOSCOPY
A.B.N. 98 050 413 379

ENDOMED PTY. LTD.
POST OFFICE BOX 445,
STRATHPINE QLD. 4500

orders@endomed.com.au

TELEPHONE 07 3881 1883
1800 773 474
FACSIMILE 07 3881 0211

or on the body and is not dependent on being metabolized for the achievement of its primary intended purposes. Therefore, 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 (June 2011), available at *https://www.fda.gov/RegulatoryInformation/Guidances/ucm2589*

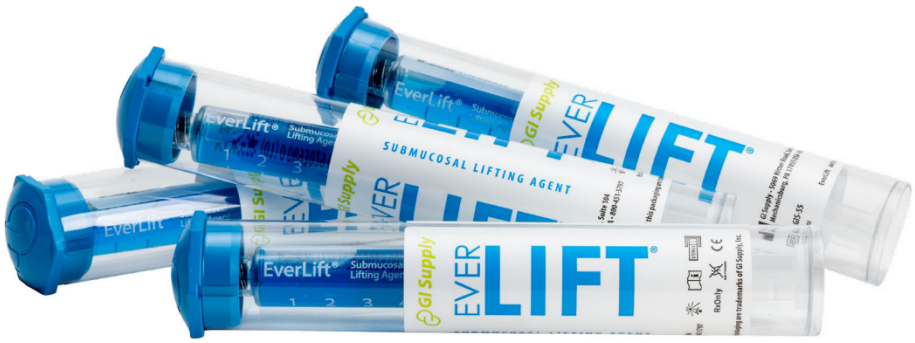
20. Will EverLift comply with the new European Medical Device Regulation (MDR)?

Yes, EverLift is GI Supply's first product to be approved for a CE Mark under MDR. The MDR replaces the existing Medical Devices Directive (MDD), and has much stricter requirements to prove the safety of devices for both patients and users. In addition MDR requires improved product traceability, greater post-market surveillance and updated labelling & documentation. EverLift is classified as a class II device under MDR.

21. What is the barcode/GTIN Number for EverLift®?

Following are the GTIN numbers for EverLift®:

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



ENDOMED PTY. LTD.
SPECIALISING IN ENDOSCOPY
A.B.N. 98 050 413 379

ENDOMED PTY. LTD.
POST OFFICE BOX 445,
STRATHPINE QLD. 4500

orders@endomed.com.au

TELEPHONE 07 3881 1883
1800 773 474
FACSIMILE 07 3881 0211