

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 10mL of lifting agent with the following ingredients:

- Water**
- Glycerin**
- Hydroxyethyl**
- Methylene Blue**
- Cellulose**
- Benzyl Alcohol** ⚠
- Sodium Phosphate**
- 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 endoscopic 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. Rarely, local bleeding, inflammatory reaction, and/or perforation could occur which may or may not be associated with EverLift. Any serious incident that has occurred in relation to the EverLift device should be reported to GI Supply and, if applicable, to the competent authority of the Member State in which the user/patient is established.

DIRECTIONS FOR USE

Open the tray and remove the syringe.

Nederlands

EverLift®

Submucosale Lifting Agent

GEbruiksAAnwijZing

OMSCHRIJVING
EverLift submucosale lifting agent is een steriele, blauwgekleurde emulsie voor gebruik bij endoscopische resectieprocedures en/of peritoneale endoscopische onderzoeken in het bovenste en de onderste maagstrikgebied, zoals de oesophagus, de maag, de darm en de endeldarm, bedoeld om de afwijking te verwijderen en te verminderen.
Submucosale en de uitwendige spierlaag te verhogen te brengen.

Samenstelling

Iedere stoomsteriliseerde spuit bevat 10 ml lifting agent met de volgende ingrediënten:

- Water**
- Glycerin**
- Hydroxyethyl**
- Methylene Blue**
- cellulose**
- Benzyl Alcohol** ⚠
- Natriumfosfaat**
- Kaliumfosfaat**

INDICATIE VOOR GEbruIk

EverLift Submucosal Lifting Agent is geïndiceerd voor gebruik bij gastro-intestinale endoscopische procedures voor submucosale verhoging van poliepen, adenomen, vroeg stadium van andere gastro-intestinale lesions voorafgaand aan excisie met een strik of ander geschikt endoscopisch apparaat.

CONTRA-INDICATIES

EverLift is contra-indiceerd bij patiënten met een bekende overgevoeligheid voor een van de ingrediënten in het product.

⚠ **Niet voor pediatrisch gebruik.**

⚠ **Niet voor gebruik bij zwangere of zogende vrouwen.**

WAARSCHUWINGEN EN VOORZORGSMAATREGELEN

De endoscopist, verpleegkundige of endoscopische technicus die EverLift submucosale injecteert moet ervaren in submucosale injectietechnieken.

EverLift is een product voor gebruik met één patiënt. Het is steriel, tenzij het product is beschadigd. Leaking van product kan een teken van schade zijn. Niet gebruiken als het product beschadigd is. Gebruik ongebruikt product vóór de spuit geopend. Om kruisbesmetting te voorkomen, mag elke spuit slechts bij één patiënt worden gebruikt en nooit opnieuw worden gebruikt.

Een onbedoelde injectie van een lifting agent in de peritoneale holte moet zorgvuldig worden gecontroleerd op bijwerkingen. In zeldzame gevallen kunnen lokale bloedingen, ontstekingsreactie en/of perforatie optreden, al dan niet in verband worden gebracht met EverLift. Eerste incidenten die voortvloeien uit EverLift-injectie moeten worden gemeld aan de competentie autoriteit van de lidstaat waar de gebruiker/patiënt is gevestigd.

GEbruiksAAnwijZingEN

Open de lade en verwijder de spuit.

Controleer de spuit op eventuele schade. Gebruik een aseptische methode om de spuit aan de heffingapparaat te verbinden.
Een 23-gauged endoscopische procedure kan een naaldsteek van 4 mm of minder voor de procedure noodzakelijk zijn. Na de naald voor het injecteren met EverLift. Met de naald ingeprikt, kan de naald worden verhoogd door het werkkanalen van de endoscoop.

Wanneer de naald correct is gepositioneerd, steek de tip punt onder een hoek van 30°-45° ten opzichte van de duim van de submucosale ruimte van het maagstrikgebied, waarbij u ervoor zorgt dat de punt van de naald zich volledig onder het slijmvlies bevindt.

⚠ **OPGELET:** *Spice of naald niet toedicht op het oppervlak van de naald, anders kan de naald te verwarmen of te versmoren of de lifting-agent reakties in de peritoneale holte.*
De verpakking en het partiturnummer staan op de lade van de spuit. Het product heeft een houdbaarheids- en een vervangings- en verbruiksdatum. Het is raadzaam om de houdbaarheids- en vervangingsdatum van de spuit te controleren, stop dan de injectie op plaats de naald voorschrijft verder in de submucosa.

De maximale toegestane dosis is 50 mL per patiënt.

Twee of zwaier letten op de volvoeding van de injectie en voordat u de naald uit de submucosale ruimte verwijderd om schade van het middel in het colen kunnen door druklooping te voorkomen.

Deponeer het product na gebruik in de daarvoor bestemde medische afvalcontainer.

BESCHRIJVING VAN SYMBOLEN

		Temperatuurlijmit
		Droog bewaren
		Niet gebruiken als verpakking beschadigd is!
		Niet opnieuw gebruiken
		Particodes
		Catalogusnummer
		Opgeliefde wetgeving mag GI apparaten alleen voor RxOnly
		Medisch apparaat

KLIANTSERVICE

GI Supply - 5069 Ritter Road, Suite 104
Mechanicsburg, PA 17055 USA - 800.451.5797
8.30 - 17.00 EST, Maandag-vrijdag - www.gi-supply.com
orders@gi-supply.com

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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 waste container.


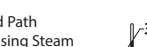

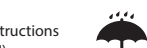




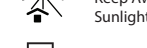







STORAGE AND SHELF LIFE

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.

The product has a shelf life of two years, with an expected device lifetime of the duration of the patient's endoscopic procedure. If used prior to the labeled expiration date and according to the instructions for use, the device is safe and effective for the stated indications.



DESCRIPTIONS OF SYMBOLS

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		Behouden
		Niet gebruiken als verpakking beschadigd is!
		Niet opnieuw gebruiken
		Particodes
		Catalogusnummer
		Opgeliefde Federale wet restricties zijn dees device te sale by or on the order of a physician
		Medisch apparaat

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
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


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


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


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


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



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


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



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



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

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