Diversatek™
Healthcare

EZ-Ject™
Injection Needle

Instructions for Use

Read carefully prior to use.

Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

Diversatek Healthcare

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EZ-JECT™ INJECTION NEEDLE

Instructions for Use

Read carefully prior to use.

Part Number	Description	Shelf Life	Quantity
1186-01	EZ-Ject Injection Needle, 5mm, 22g, 180cm	3 years	10/CS
1186-02	EZ-Ject Injection Needle, 5mm, 22g, 230cm	3 years	10/CS
1186-03	EZ-Ject Injection Needle, 5mm, 25g, 230cm	3 years	10/CS
1186-04	EZ-Ject Injection Needle, 5mm, 19g, 180cm	3 years	10/CS

INTENDED USE

The Diversatek Healthcare **EZ-Ject™ Injection Needle** is an endoscopic accessory intended to introduce a sclerosing agent, vasoconstrictor, or other solutions into selected sites to control actual or potential bleeding lesions in the digestive system or to inject liquid to aid in polypectomy procedures.

INTENDED USER

The users of the Diversatek Healthcare instruments must be specialists in their fields. An appropriate and specific training for preparation, care and maintenance of the flexible instrument is required.

INTENDED POPULATION

This device is intended for both adult and pediatric patients according to the physician recommendation taking into account the contraindications.

PRODUCT DESCRIPTION

The injection needle is made of a stainless-steel needle (1) attached to a flexible catheter with an inner sheath (2) at the distal end and a handle (3) with a luer-lock piston (4) at the proximal end.

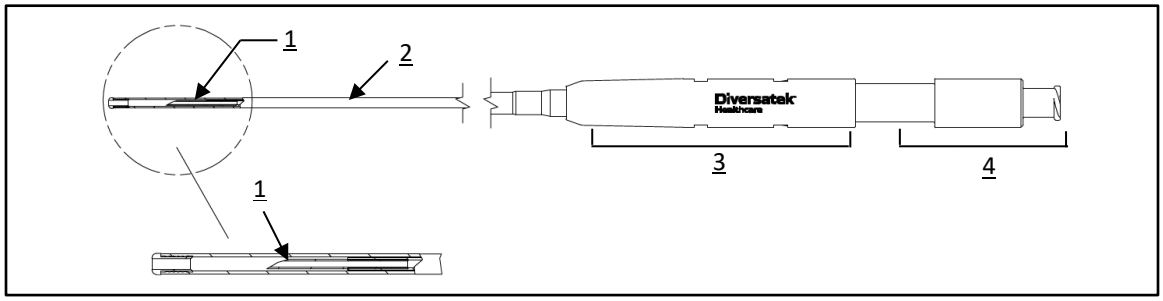

Figure 1: Drawing of EZ-Ject Injection Needle
1. Stainless Steel Needle 2. Catheter 3. Handle 4. Luer-Lock Piston

CONTRAINDICATIONS

Contraindications are those applicable to injection therapy and include, but may not be limited to, those patients allergic to sclerosing agent and patients with lesions inappropriate for injection therapy with sclerosing agents.

INSTRUCTIONS FOR USE

1. Check to ensure that the needle is operating properly by pushing the piston in and out while holding the handle. The handle is equipped with two stops. You should feel a "click" when the needle is in the fully deployed position and when the needle is in the fully retracted position.
2. Prepare a luer-lock adaptable syringe with the liquid solution to be injected. Make sure that the needle is in its fully exposed position. (Figure 2)

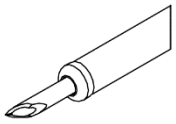

Figure 2: Exposed Needle

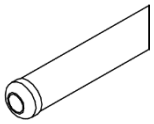

Figure 3: Retracted Needle

3. Attach the syringe to the needle via the luer-lock connection at the proximal end of the handle and flush out any air in the catheter using the liquid solution. Visually verify that the liquid agent reaches the distal tip of needle, and all air has been evacuated from the inner catheter.
4. Retract the needle into its catheter to fully withdrawn position. (NOTE: the luer-lock piston part of the handle is retracted – Position UP) (Figure 4)
5. Introduce the catheter into the working channel of an appropriately sized endoscope. Advance catheter in small increments until the catheter emerges from the scope.
6. Fully deploy the needle until you feel the piston "click" into place. (NOTE: the luer-lock piston part of the handle is fully pushed into the outer part of the handle – Position DOWN) (Figure 5)
7. Proceed with the injection at an oblique angle to the tissue site.
8. Following the injection(s), retract the needle until the needle piston "clicks" into the fully retracted position. (Figure 4 Position UP)
   NOTE: When using the irrigation flush port, the needle must be fully retracted until the piston "clicks" into the retracted position. Prepare a luer-lock adaptable syringe with the irrigation agent to be injected and attach the syringe to the irrigation flush port via the luer-lock protruding from the side of the lateral connection port.
   NOTE: When inserting or withdrawing device from scope, ensure that the distal end of the scope is not in the retroflexed position.
9. Upon completion of the procedure, remove the instrument from the scope.
   NOTE: When advancing or withdrawing the device from the endoscope, it is important to ensure that the needle is in its fully retracted position to avoid damaging the working channel of the endoscope (the inner luer-lock piston part of the handle is retracted – Position UP) (Figure 4).

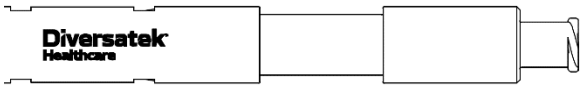

Figure 4: Piston Position "UP"

Figure 5: Piston Position "DOWN"

POTENTIAL COMPLICATIONS

1. Fever, allergic reaction to medication, perforation, sepsis.
2. Respiratory depression or respiratory arrest, cardiac arrhythmias, or cardiac arrest.

WARNINGS AND PRECAUTIONS

1. Please read carefully and follow all safety operating instructions and warnings before first application of the device.
2. A previous knowledge regarding handling and operation is required and essential.

3. Unpack the instrument carefully and examine the devices for any possibility of damage. In case of any damage or missing items contact your distributor immediately. If the package is damaged, the sterility of the device is not guaranteed.
4. Sclerotherapy & endoscopic needles are composed by a catheter and should never be manipulated with its catheter winded as this may damage the device and make its usage impossible! For ethanolamine and cyanoacrylate only use a 19GA needle (#1186-04).
5. Products marked “single-use” are for single-use only. Do not reuse, reprocess, or re-sterilize single-use products. The materials used in the manufacture of the device may not withstand repeated reprocessing. The device may not perform as intended by the manufacturer if it is reused. This may lead to failure of the device to perform as intended and/or material degradation, which may result in patient injury, illness or death. Reuse, reprocessing, or resterilization may also increase the risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
6. Injection needles are made of a catheter and should never be manipulated with the catheter coiled as this may damage the device and make its usage impossible.
7. Report any serious incident that has occurred in relation to the device to the distributor or manufacturer or competent authority of the member state.

STORAGE

- This device is delivered sterilized and should remain in its original packaging to maintain this sterile state until first use.
- Do not put any objects on the instrument or its package.
- Do not store the instruments near aggressive chemical products.
- Do not expose the instruments to direct or indirect sunlight or other ultra-violet rays.
- Keep in dry area.

PRODUCT DISPOSAL

After use, these products may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

DESCRIPTION OF SYMBOLS USED ON LABELS

	Manufactured for
	Use-by date (YYYY-MM-DD)
	Lot number
	Part number
	Sterilized using ethylene oxide
	Do not re-use
	Consult instructions for use
	Do not use if package is damaged

Not made with natural rubber latex

Keep away from sunlight

Keep dry