



EndoTNeedle

Endoscopic Injection Needle

REF ET1310



Instructions for Use

Read this document in its entirety prior to use

Rx Only
SINGLE USE, DISPOSABLE

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Intended Use

Endoscopic injection needles are used for the endoscopic injection of legally marketed sclerotherapy agents and dyes into esophageal or colonic varices.

Contraindications

Contraindications for this device are those applicable to injection therapy and include, but may not be limited to, those patients allergic to dyes, sclerotherapy or vasoconstriction agents and patients with lesions inappropriate for injection therapy with sclerotherapy or vasoconstriction agents.

Warnings and Precautions

This device is sharp. Use same care as for any other surgical device to avoid punctures or cuts to hands, gloves, etc.

Do not use if the sterile packaging is compromised, any abnormalities are found or if the instrument is not operating properly.

When inserting or withdrawing device from endoscope, ensure the endoscope is not in a retroflexed position and the needle is fully retracted into outer sheath before putting device through endoscope channel.

Inspection

1. Inspect the package containing the device. If any damage is noticed, do not use the device as sterility may be compromised.
 2. Peel open the pouch and remove the device. Visually inspect the device for kinks, loose or broken parts. Form the device into three (3) 8" diameter loops for 230 cm or two (2) 8" diameter loops for 160 cm length device. Check to ensure that the needle is operating properly by pushing the needle piston in and out while holding the handle. The needle 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.
 3. Retract the needle into the outer sheath before inserting the device into the working channel of the endoscope.
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Instructions

1. Prepare a Luer-Lock adaptable syringe with the agent to be injected.
2. Make sure that the needle is in its fully retracted position. Then attach the syringe to the needle via the Luer-Lock at the top of the needle piston and flush out the air in the piston using the liquid agent. Visually verify that the liquid agent reaches the distal tip of needle and all air has been evacuated from the inner catheter.
3. Introduce the catheter into the working channel of an appropriately sized endoscope. Advance in small increments until the catheter emerges from the endoscope. If the endoscope is equipped with an elevator, raise the elevator fully before loading.
4. Fully deploy the needle until you feel the piston “click” into place.
5. Proceed with the injection at an oblique angle to the tissue site.
6. Following the injection(s), retract the needle until the needle piston “clicks” into the fully retracted position.

NOTE: When inserting or withdrawing device from endoscope, ensure that the distal end of the endoscope is not in the retroflexed position.

NOTE: When the device is being advanced or withdrawn 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.

7. Upon completion of the procedure, remove the instrument from the endoscope. If the endoscope has an elevator, it must be lowered before withdrawing the device.

Disposal

Dispose of the device after use in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
















Storage

Store sterile instruments at room temperature.

Do not expose to solvents, radiation, UV light or any other substance or environment that could compromise the sterility of the unit.

Do not place any objects on the device or packaging.

Labeling Symbols


	Consult Instruction for Use
	Single use - Do not reuse
	Do not resterilize
	Keep dry
	Ethylene Oxide Sterilization
	Catalog Number / Product Code
	Lot Number
	Use by Date
	Date of manufacture
RxOnly	Federal (USA) Law restricts this device to sale by or on the order of a physician
	Manufacturer
	Quantity of devices in pouch
	Quantity of devices in box
	Do not use if package is opened or damaged
	European Community Conformity Marking
	European Community Authorized Representative



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