Injection Needle (single use)
Instructions for Use

Micro-Tech (Nanjing) Co., Ltd
IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech.

INTENDED USE

The injection needle is intended for use in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varies and for submucosal dye marking in the GI tract.
1. Acute esophageal variceal bleeding.
2. Markings before surgery on polyps and early stage cancer and markings for review in the short term.
3. Bleeding after the removal of polyps or early stage cancer.
4. Bleeding from blood vessels in ulcers.
5. Bleeding after sphincterotomy.
6. Inject flat polyps or early stage cancer to help in removal.

CONTRAINDICATIONS

1. Poor physical fitness so that the patient can’t tolerate endoscopy and endoscopic treatment
2. A narrow upper digestive tract so that an endoscope cannot go through
3. Severe coagulation disorders or hemorrhagic diseases
4. Allergic to this product or the medicines used in surgery
5. Not suitable to be treated by the instrument after being diagnosed
6. Uncooperative patients or their families

POTENTIAL COMPLICATIONS

1. Esophagus obstruction or stenosis, fever, perforation, bleeding.
2. Infection, sepsis, etc.
3. Potential complications that are not known or observed.
WARNINGS

1. The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess. Re-use, re-sterilization or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, re-sterilization or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, re-sterilized or reprocessed.

2. Do not use this instrument for any purpose other than its intended use.

3. The product is only intended for adult populations.

4. This device is not made with natural rubber latex.

5. The instrument is intended for use under the direct supervision of a suitably trained physician only. A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.

6. Confirm that the endoscopy view is clear before use. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhage or mucous membrane damage. Damage to the endoscope and/or the instrument may also occur.

7. In case the needle couldn’t retract into the outer sheath, DO NOT try to remove the instrument through the endoscope channel. It could be removed along with the endoscope together.

8. The operation should be gentle and stable. Do not apply excessive force in operation.

9. Patient should be informed and expressed his/her acceptance for the details of the operation and all the potential risks and complications, which may lead to injury, illness or death of the patients.

10. Please read the instructions for use entirely before use.

【Product Name】Injection Needle (single use)
【Packaging】Packed in Pouch
【Production Date】See packaging
【Sterilization】Sterilized by EO (ethylene oxide) gas
【Shelf Life】3years
【Compatible Working Channel】≥ φ2.8mm
STRUCTURE

The injection needle consists of a stainless steel needle attached to plastic inner sheath and luer lock hub where a standard syringe can be attached for injection of materials through the lumen of the needle into tissue as Figure 1.

![Figure 1 Structural Sketch of the Injection Needle](image)


PREPARATION

1. Reference the product label and choose the appropriate device.
2. Contents supplied STERILE.
3. Inspect the package before use for any damage. Do not use if package is damaged. Open the package carefully after verifying the shelf life.
4. Before use, please check the insertion patients body parts, ensure that no sharp edge.
5. If this device shows any signs of damage and suspicious problems, do not use. Do not attempt to repair nonfunctional or damaged device.
6. Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
7. Operate the handle and verify needle advancement. Do not use if the needle doesn't deploy.
8. Release the lock on the handle to retract the needle into the outer sheath. Do not use if the needle doesn't retract into the sheath.
9. Secure the syringe onto the luer port on the handle.
INSTRUCTIONS FOR USE

1. Before use, securely attach a prefilled syringe to the luer lock hub on the device (Refer to Figure 2), then inject the solution into the injection needle to remove the air and flush the Inner sheath(Available injection solutions contain physiological saline, glycerol and fructose, fibrinogen).

![Figure 2]

Note: For proper sealing performance, applicable syringe with threaded port is recommended.

2. Retract the needle into the sheath and put the injection needle into the endoscope’s working channel. Slowly advance the device into the channel of the endoscope until its distal end is exposed out of the endoscope’s working channel’s distal end. (Refer to Figure 3).

![Figure 3]

3. Adjust the endoscope to the target injection position and maintain, with the outer sheath in endoscopic view, advance the needle into the accurate position slowly(Refer to Figure 4).
4. Thoroughly press the handle to limit position, so the needle tip extends out of the outer sheath. Advance the needle into the mucosa, then using the attached syringe perform the injection as required (Refer to Figure 5).

Note: Press the handle halfway, would cause needle retraction when injecting into the mucosa.

5. When the injection is complete, depress the plastic shell handle ring to retract the needle into the outer sheath. Repeat the procedure as necessary.
6. Upon completion of the procedure, remove the instrument from the endoscope with needle retracted into the outer sheath.
7. Upon completion of the procedure, dispose of the device according to the institutional guidelines for biohazard medical waste and local regulatory requirements.

**STORAGE**

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment.
Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.
The product shelf life is 3 years.
PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

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