

Spray Catheter Instructions for Use



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 Spray Catheter is used for lavage, spraying of a stain, or solution, in the gastrointestinal tract by passing through the working channel of a flexible endoscope.

CONTRAINDICATIONS

The contraindications of the spray catheter include but not limited to:
The same contraindications as those of the primary endoscopic procedure;

POTENTIAL COMPLICATIONS

Those associated with the primary endoscopic procedure including but not limited to: perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

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. Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
6. **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.
7. Confirm that the endoscopic 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.
8. Products supplied sterile are ready to use. Prior to use, check the expiry date on the package. If the expiry date has lapsed, do not use. Do not use the product if the package is damaged or opened.

[Product Name] Spray Catheter

[Packaging] Packed in Pouch

[Manufacturing Date] See packaging

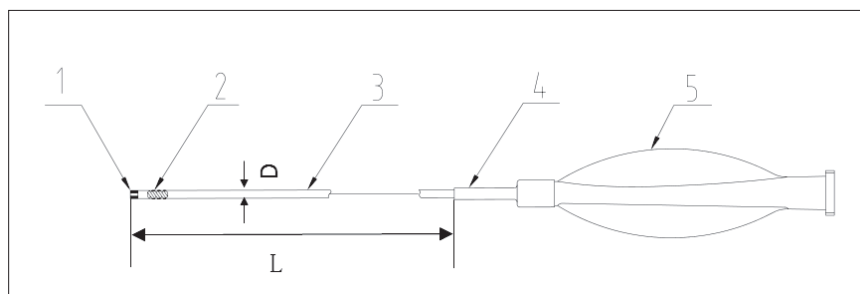
[Sterilization] Sterilized by EO (ethylene oxide) gas

[Shelf Life] Five years

[Compatible Working Channel] ≥ 2.8 mm

STRUCTURE

The structure of the Spray Catheter includes nozzle, screw, catheter, protective and handle.



1. Nozzle; 2. Screw; 3. Catheter; 4. Protective sleeve; 5. Handle

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. Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
5. Before use, check the device for any damage.
6. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.

INSTRUCTIONS FOR USE

1. Under endoscopic view, identify the area of interest.
2. Insert the spray catheter into the working channel using short movements until the distal tip is visible in the endoscopic view.
3. Connect the handle of the spray catheter to a syringe, and then carry out lavage, spraying of a stain, medical solution or contrast medium, etc. under direct endoscopic visualization.
4. After application, withdraw the spray catheter from the channel exercising care when the distal tip exits the endoscope biopsy valve.

Caution: Rapid withdrawal may lead to splashing of the injection media. Caution should be used and appropriate personal protection guidelines followed.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Dispose the device in accordance with hospital, local and administrative laws and regulations.

STORAGE

The product should be stored in a cool, dry, clean, well-ventilated environment. Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.

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