MICRO-TECH ™
ENDOSCOPY

Single-Use Marked Spring Tip Guidewire

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 Single-Use Marked Spring Tip Guidewire is used to endoscopically introduce an esophageal dilator within the upper gastrointestinal tract.

CONTRAINDICATIONS

None known

POTENTIAL COMPLICATIONS

Dilatation of, but not limited to, peptic esophageal strictures, caustic strictures, upper esophageal web, lower esophageal rings, and palliation of esophageal carcinoma.

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 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.

8. The guidewire should not be advanced if resistance is met without determining the cause and taking remedial action.
9. Should there occur any irregularities, dispose the instrument and replace it with a new one.

【 **Product Name** 】 Single-Use Marked Spring Tip Guidewire

【 **Packaging** 】 Packed in Pouch

【 **Production Date** 】 See packaging

【 **Sterilization** 】 Sterilized by EO (ethylene oxide) gas

【 **Shelf Life**】 2 years

【 **Compatible Working Channel** 】

REF	Working channel ø (mm)
DG-18-08-21	≥2.0

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 Guidewire to ensure that there are no sharp edges.
6. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.
7. Before use, it should be noted that the diameter of the guide wire should be smaller than the diameter of the channel, and the length of the guide wire should be greater than the length of the channel.

Note: The marking bands are used to determine the location of the distal spring tip from the dentures.

2 rings: 400mm **3 rings: 600mm** **4 rings: 800mm**

5 rings: 1000mm **6 rings: 1200mm** **7 rings: 1400mm**

INSTRUCTIONS FOR USE

1. Perform screening endoscopy and identify strictured area.
2. Insert the spring tip of the guide wire into the appropriate endoscopic channel and advance until it is endoscopically visualized beyond the tip of the scope.
3. When the guide wire is in position beyond the strictured area, withdraw the endoscope and slowly insert the dilator along the other end of the guide wire to the strictured area.
4. Marked position of guide wire and dilator should be observed during operation, to prevent damage to human tissues or organs.
5. Remove the guide wire and the dilator together after completing the expansion of the strictured area.

STORAGE

Store the instrument in the sterile package at room temperature in a clean and dry environment.
Do not store the instrument in direct sunlight. Ensure that the package is not crushed by surrounding objects during storage.

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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