MICRO-TECH™
ENDOSCOPY

Reliant™ Multistage Dilatation Balloon Catheter

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 Reliant™ Multistage Dilatation Balloon Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the gastrointestinal tract.

CONTRAINDICATIONS

The contraindications include, but are not limited to, the following:

- Severe cardiopulmonary insufficiency or thrombasthenia;
- The patient's inability to withstand endoscopy procedures;
- Severe active gastroesophageal varicosity by portal hypertension;
- Aortic aneurysm or cardiopulmonary failure;
- Severe active internal hemorrhoid or varicosity;
- Acute inflammation or active ulcerative colitis;
- Multiple small intestinal obstructions due to extensive adhesions;
- Asymptomatic rings, webs or strictures;
- Inability to advance the dilation balloon through the area of stricture;
- Known or suspected perforation;
- Severe inflammation or scarring near the site of dilation.

POTENTIAL COMPLICATIONS

Potential complications associated with balloon dilatation include, but are not limited to:

- Pancreatitis
- Cholangitis
- Perforation
- Hemorrhage
- Hematoma
- Sapraemia
- Infection
- Allergic reaction to contrast agent or medication
- Hypotension
- Respiratory depression or arrest
- Cardiac arrhythmia or arrest

WARNINGS

- **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.
- Do not use this instrument for any purpose other than its intended use.
- The product is only intended for adult and adolescent populations.
- This device is not made with natural rubber latex.
- Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
- 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.
- 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.
- If excessive resistance is met during the procedure, confirm the cause of the resistance and take remedial action before proceeding.

- If the balloon bursts during the procedure, stop the procedure immediately and take remedial action.

【 Product Name 】Reliant™ Multistage Dilatation Balloon Catheter

【 Packaging 】Packed in Pouch

【 Production Date 】 See packaging

【 Sterilization 】 Sterilized by EO (ethylene oxide) gas

【 Shelf Life】 3 years

【 Compatible Working Channel 】≥ø2.8mm Olympus or ≥ø3.2mm Other

PREPARATION

1. Reference the product label and choose the appropriate device. Refer to the compatible working channel.
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 expiration date.
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. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.
6. The balloon is provided with a guidewire lock, located at the guidewire luer port. This lock needs to be in the OFF position to advance or retract the guidewire. LOCK the guidewire prior to introduction into the endoscope.
7. If desired, the 0.035 guidewire can be removed and the catheter backloaded onto a suitable 0.035 guidewire insitu. It is recommended that the guidewire port be flushed with saline prior to loading the catheter onto the guidewire.
8. Do not pre-inflate or test the balloon before insertion.
9. Utilizing an appropriate 60ml balloon inflation device with pressure monitor, prime the syringe per the manufacturer instruction for use. Inflate the balloon only with sterile water, saline or contrast medium mixture.

INSTRUCTIONS FOR USE

1. Attach the primed inflation device to the catheter hub, apply and hold a vacuum. Remove the protective sleeve from the balloon.
2. Apply a silicone spray to the balloon surface to facilitate passage through the endoscope working channel.
3. Opening or removal of the endoscopes biopsy valve - rubber valve, may help facilitate easier passage of balloons larger than 12mm.
4. Maintain a vacuum to the catheter during introduction into the endoscope.

   WARNING: If excessive resistance is met during the procedure, confirm the cause of the resistance and take remedial action before proceeding.
5. Slowly advance the balloon catheter into the endoscope using short deliberate movements, under direct endoscopic or fluroscopic visualization.
6. Ensure the proximal balloon catheter is visible in the endoscopic view, prior to inflating the balloon. Once the balloon's position is confirmed, inflate the balloon with the inflation device.

   WARNING: Never use Air or Gas to inflate the balloon.
7. The Reliant™ Multistage Dilatation Balloon Catheter is capable of attain 3 distinct sizes, at the associated inflation pressures. Adjust the pressure of the balloon to attain the smallest size, according to the recommended working pressure on the package label. Larger diameters can be achieved with higher inflation pressures based on the pressure/diameter tag label near the hub on the proximal end of the catheter. The balloon may burst if excessive pressure is applied.

   WARNING: If the balloon bursts during the procedure, stop the procedure immediately and take remedial action.

   Note: If the balloon bursts, do not withdraw the balloon through the endoscope. Carefully remove the burst balloon and endoscope together as a single unit.
8. Carefully observe the balloon pressure during Dilatation. Minor adjustments may need to be made to maintain the appropriate pressure. This is normal.
9. To remove the balloon, apply a negative pressure using the inflation device. Under direct endoscopic view, ensure that all liquid is withdrawn from the balloon before slowly removing the catheter from the endoscope.

   Note: Ensure all fluid is removed before attempting to remove the balloon. Depending upon the inflation balloon size and chosen medium, this may take between 10-30 seconds.

   Note: Resistance can be reduced by straightening the endoscope, where possible, prior to removal of the catheter.

Note: Do not forcefully withdraw the balloon from the endoscope. If significant resistance is encountered, removal of the endoscope along with the compromised balloon may be required in order to prevent damages to the endoscope. Remove the balloon catheter from the endoscope by cutting the proximal end of the balloon.

10. Upon completion of the procedure, dispose of the device(s) as per institutional guidelines for biohazardous medical waste.

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.

PRODUCT DISPOSAL

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

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