

TWISTER® PLUS

English

Rotatable Retrieval Device

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The TWISTER® PLUS Rotatable Retrieval Device consists of a flexible wire/catheter and a basket with net that is extended and retracted from the outer sheath using a three-ring handle. The device is 230cm in length and 2.5mm in diameter.

INTENDED USE

The TWISTER PLUS Rotatable Retrieval Device is intended to be passed through an endoscope's working channel to remove foreign body objects, such as polyps and food boluses.

WARNINGS

- Do not attempt to repair the device.
- For single use only. Do not reuse, reprocess or resterilize.
- Do not use if sterile barrier is damaged. If damaged, call Customer Service or your Merit Medical Endotek representative.
- Used product and packaging should be disposed of in accordance with hospital, administrative and/or local government policy.
- Instructions for Use should be read thoroughly as failure to follow the instructions for use may lead to serious clinical complications.
- Use of this device should be restricted to use by or under the supervision of physicians trained in endoscopic procedures.
- Reusing, reprocessing or re sterilizing 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, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection including, but not limited to, transmission of infectious disease(s) from one patient to another.

PRECAUTIONS

- Inspect the TWISTER PLUS Rotatable Retrieval Device and packaging for damage prior to use. Do not use product if opened or damaged. Confirm the product is consistent with the package label. Contact Customer Service or your Merit Medical Endotek Representative to report and replace damaged product.
- The TWISTER PLUS Rotatable Retrieval Device requires a minimum working channel of 2.8mm.
- Any use of the product, other than as indicated in the instructions, is not recommended.

PREPARING FOR USE

1. Open and remove the TWISTER PLUS Rotatable Retrieval Device from the pouch.






Note: Uncoil the TWISTER PLUS Rotatable Retrieval Device before continuing with preparation to avoid damage.

2. The TWISTER PLUS Rotatable Retrieval Device should be visually inspected for kinks and complete product integrity. If any damaged is observed, do not use the TWISTER PLUS Rotatable Retrieval Device and contact Customer Service or your Merit Medical Endotek representative.
3. The TWISTER PLUS Rotatable Retrieval Device should be tested prior to being passed through the endoscope's working channel. Test the device by sliding the finger grip forward and backward. The flexible wire and basket with net should completely extend from and retract back into the tip of the catheter.
4. Verify the working channel of the endoscope is a minimum of 2.8mm to ensure compatibility with the TWISTER PLUS Rotatable Retrieval Device.
5. The TWISTER PLUS Rotatable Retrieval Device is now ready for clinical use.

INSTRUCTIONS FOR USE

Note: The TWISTER PLUS Rotatable Retrieval Device should be advanced through the endoscope's working channel using short and precise movements to mitigate potential unintended damage to the device or endoscope.

1. Identify the foreign body endoscopically and advance the TWISTER PLUS Rotatable Retrieval Device through the endoscope's working channel until the distal end of the catheter is endoscopically visible.
2. The distal end of the catheter should be advanced slightly distal to the foreign body however it is not recommended to advance the device if the foreign body has blocked the entire lumen. The TWISTER PLUS Rotatable Retrieval Device should be opened completely by advancing the handle forward until it stops. Endoscopically confirm the net is fully open.
3. The TWISTER PLUS Rotatable Retrieval Device should be positioned over the foreign body and rotated into position by rotating the device handle. For best results, the foreign object should be centered or proximal in the net prior to closure.
4. To secure the foreign body, retract the handle until the net closes around the foreign body. The net should be carefully opened and closed with gentle traction applied until the entire foreign body is retrieved. Excessive traction may cause damage to the device and/or the foreign body.
5. The TWISTER PLUS Rotatable Retrieval Device should then be retracted toward the endoscope so that it is visible, yet not compromising the endoscopic view to ensure visibility during removal of the device and foreign body.
6. Once the scope, device and foreign body have been removed, the foreign body can be collected from the TWISTER PLUS Rotatable Retrieval Device by advancing the handle forward to open the net. The foreign body should be processed per procedural standards.
7. Once retrieval is complete, the device should be closed by advancing the handle and removed from the endoscope's working channel.

	Caution: Consult accompanying documents. Read instructions prior to use.
	Single use.
	Do not use if package is damaged
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Sterilized using ethylene oxide

This product is protected by one or more of the following United States Patents: 9,101,342; 8,858,567.

 MERITMEDICAL
ENDOTEK®

CE 0473

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