

COOK®

MEDICAL

**PreCurved Triple Lumen Sphincterotome
w/Preloaded Wire Guide**



17874/0413

INTENDED USE

This device is used for cannulation of the ductal system and for sphincterotomy. The preloaded wire guide aids in bridging difficult strictures during ERCP.

NOTES

The device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.

Do not use this device for any purpose other than stated intended use.

If package is opened or damaged when received, do not use. Visually inspect with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Cook for return authorization.

Store in a dry location, away from temperature extremes.

Use of this device restricted to a trained healthcare professional.

CONTRAINDICATIONS

Contraindications include those specific to ERCP and any procedures to be performed in conjunction with sphincterotomy.

Contraindications to sphincterotomy include, but are not limited to: coagulopathy and inability to properly position the sphincterotome cutting wire.

POTENTIAL COMPLICATIONS

Potential complications associated with ERCP include, but are not limited to: pancreatitis, cholangitis, aspiration, perforation, hemorrhage, infection, sepsis, allergic reaction to contrast or medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

PRECAUTIONS

Refer to package label for minimum channel size required for this device.

Maximum rated input voltage for this device is 1.5 kVp-p.

Any electrosurgical accessory constitutes a potential electrical hazard to patient and operator. Possible adverse effects include, but are not limited to: fulguration, burns, nerve and/or muscle stimulation and cardiac arrhythmia.

Before using this device, follow recommendations provided by electrosurgical unit manufacturer to ensure patient safety through proper placement and utilization of patient return electrode. Ensure a proper path from patient return electrode to electrosurgical unit is maintained throughout procedure.

Switch electrosurgical unit to "off" position when it is not in use.

When applying current, ensure cutting wire is completely out of endoscope. Contact of cutting wire with endoscope may cause grounding, which can result in patient injury, operator injury, a broken cutting wire, and/or damage to endoscope.

If a non-protected wire guide is used in sphincterotome, it must be removed prior to applying electrosurgical current.

Do not over flex or bow tip beyond 90°, as this may damage or cause cutting wire to break.

Elevator should remain open/down when advancing or retracting sphincterotome.

Use of wire guide with metal tip ERCP devices may result in damage to external coating and/or tip of wire guide.

SYSTEM PREPARATION

1. Upon removing device from package, uncoil and straighten sphincterotome. Carefully remove precurved stylet from cannulating tip. **Note:** Do not apply manual pressure to tip or cutting wire of sphincterotome to influence orientation, as this may result in damage to device. **Note:** Do not exercise handle while device is coiled or precurved stylet is in place, as this may cause damage to sphincterotome and render it inoperable.
2. With electrosurgical unit off, prepare equipment. Active cord fittings should fit snugly into both device handle and electrosurgical unit.
3. Verify wire guide position within sphincterotome. Distal tip of wire guide should be proximal to tip of catheter.
4. Secure wire guide in position by tightening Tuohy-Borst adapter to avoid risk of wire movement.
5. Flush wire guide port. For best results, wire guide should be kept wet. **Note:** Make sure Tuohy-Borst adapter is securely tightened around wire guide prior to flushing (*See Fig.*).
6. Flush the contrast lumen to expel all air prior to cannulation.

INSTRUCTIONS FOR USE

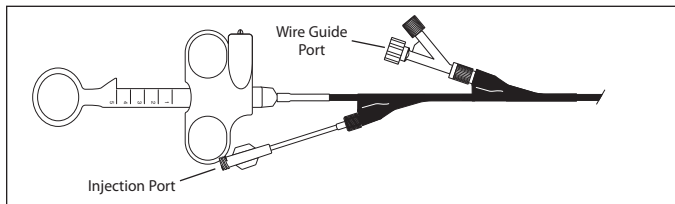
1. Advance tip of sphincterotome into endoscope accessory channel and continue to advance in short increments until device is endoscopically visible.
2. Following cannulation, contrast may be injected through injection port to fluoroscopically confirm position of device.
3. Following electrosurgical unit manufacturer's instructions, verify desired settings and proceed with sphincterotomy.
4. Upon completion of sphincterotomy, turn electrosurgical unit off.

Note: Previously placed wire guide may be left in position, in order to facilitate introduction of compatible devices.

5. Disconnect active cord from device handle and from electrosurgical unit. Wipe active cord with a damp cloth to remove all foreign matter. Store in a loose coil.

Note: Wrapping active cord tightly may damage device.

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



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