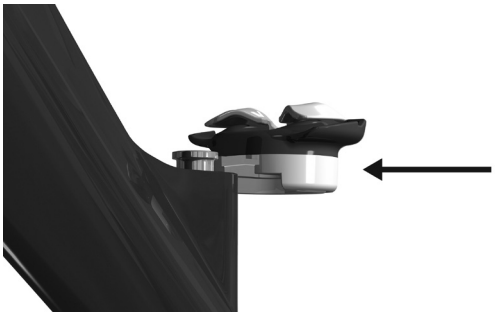
COOK MEDICAL

SnapLoc™ Wire Guide Locking Device

Instructions For Use



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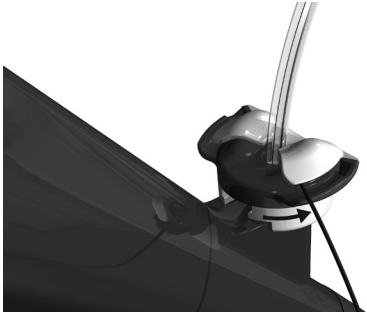

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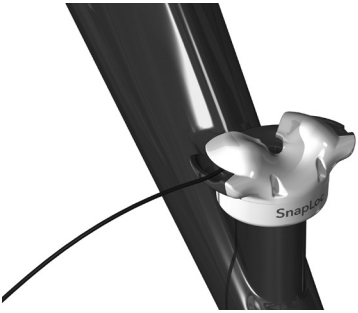

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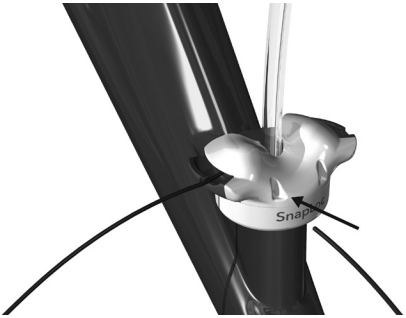

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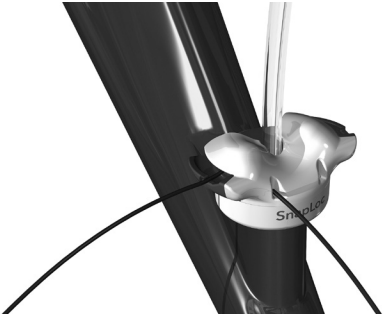


5.

6.

ENGLISH

SnapLoc™ Wire Guide Locking Device

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner). Please read all instructions before using this device.

DEVICE DESCRIPTION

The SnapLoc wire guide locking device is an accessory device that attaches to the endoscope accessory channel to lock the wire guide in place during ERCP procedures. The device is designed to be compatible with Olympus®, Pentax®, and/or FujiFilm® endoscopes.

Performance Characteristics

For optimal performance, utilize device with non-fully hydrophilic coated .025" and .035" Cook wire guides. This device can accept up to 11.5 Fr Cook catheters.

Patient Population

The device is indicated for adult use only.

Intended User

Use of this device is restricted to a trained healthcare professional.

Device Compatibility

This device requires use of a 4.2 mm duodenoscope from the manufacturer(s) listed in the table below.

Product	Endoscope Manufacturer		
	Pentax ®	Olympus ®	Fujifilm ®
SNAPLOC-O (G59683)	-	X	-
SNAPLOC-P (G59686)	X (ED34-i10T model only)	-	-
SNAPLOC-F (G59685)	-	-	X

'X' means compatible with, '-' means NOT compatible with

Contact with Body Tissue

The device has indirect patient contact.

Operating Principle

The device attaches onto the endoscope accessory channel. The device resists motion of the wire guide so other endoscopic accessory devices can be passed to the area of interest.

INTENDED USE

This device is an accessory to be used with endoscopic biliary and pancreatic devices to lock the wire guide(s) in place and to prevent reflux of bodily fluids during ERCP.

INDICATIONS FOR USE

This device is used for duodenoscope during the ERCP procedure.

CLINICAL BENEFITS

This device supports device placement or insertion during various ERCP procedures.

CONTRAINDICATIONS

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

WARNINGS

This device is designed for single use only. Attempts to reprocess, sterilize, and/or reuse may lead to contamination with biological or chemical agents and/or mechanical integrity failure of device.

If the package is opened or damaged when received, do not use. Visually inspect device. If an abnormality is detected that would prohibit proper working condition, do not use. Notify Cook for return authorization.

PRECAUTIONS

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

POTENTIAL COMPLICATIONS

This device is used with Cook biliary and pancreatic devices. Read appropriate Instructions for Use for complications associated with the procedure and device being used.

HOW SUPPLIED

This device is supplied ethylene oxide (EtO) sterile, in a peel-open pouch. The peel-open pouches are packaged in multiples, inside of a protective packaging layer. The devices may not be re-sterilized by any method. Store in a dark, dry, cool place. Avoid extended exposure to light and extremes of temperature and humidity, direct sunlight, radiation, and sharps.

INSTRUCTIONS FOR USE

1. Upon removing the device from the package, attach device to accessory channel of compatible duodenoscope. Slide SnapLoc device onto accessory channel until audible and/or tactile feedback to ensure that the device is fully seated, Figure 1.

- **PRECAUTION**: Failure to adequately engage the device with the accessory channel may result in premature detachment of device.
- **PRECAUTION**: Failure to use compatible duodenoscope may result in premature detachment of device.

2. Introduce accessory into duodenoscope through SnapLoc until device extends from duodenoscope and device is endoscopically visible.
3. For short wire exchange, lock wire guide into left or right locking positions on SnapLoc, Figure 2 and 3. Grip wire guide close to SnapLoc, locking to same side it exits the catheter to avoid translation of the wire guide. Secure the end of the wire guide into opening slot at front of SnapLoc, on the same side that the wire guide is locked, it is necessary to push past an initial resistance to fully secure the end of the wire guide, Figure 4 and 5.
4. Slowly remove catheter until increased resistance is met on device or until you reach the short point of exchange. Thereafter, unlock wire guide from SnapLoc and remove device while advancing wire guide till device tip exits the SnapLoc and re-lock wire guide. Secure the end of the wire guide as outlined in step 3 above.
   - **PRECAUTION**: Failure to reduce removal speed when approaching distal end of accessory device, may result in damage to device or wire guide looping at SnapLoc.
   - **PRECAUTION**: Failure to utilize compatible Cook 0.025" and 0.035" wire guides may result in wire guide translation and/or looping during the device exchange.
5. For long wire exchange, in short increments remove device from duodenoscope while advancing wire guide at handle hub.
6. Upon completion of the procedure, remove device from accessory channel, Figure 6.

DISPOSAL OF DEVICE

Upon completion of the procedure, dispose of the device per institutional guidelines for biohazardous medical waste.

PATIENT COUNSELING INFORMATION

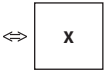
Please inform the patient as necessary of the relevant warnings, precautions, contraindications, measures to be taken and limitations of use that the patient should be aware of.

SERIOUS INCIDENT REPORTING

If any serious incident has occurred in relation to the device this should be reported to Cook Medical and the competent authority of the country where the device was used.

A symbol glossary can be found at cookmedical.com/symbol-glossary

If symbol appears on product label, X = wire guide compatibility



If symbol appears on product label, X = duodenoscope compatibility

RxOnly

STERILE | EO

This device is intended for single use only.

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