

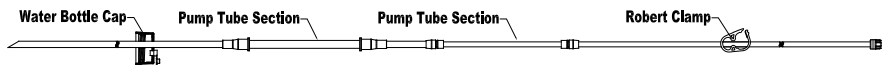
COOK®

MEDICAL

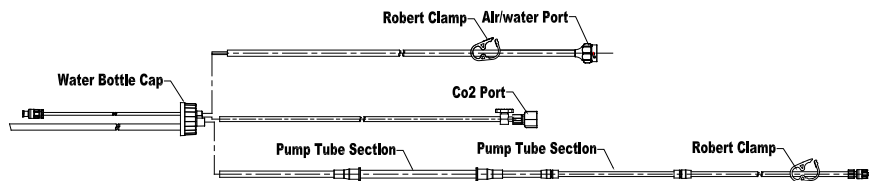
EN

Sentrus™ Irrigation and Insufflation Tubing

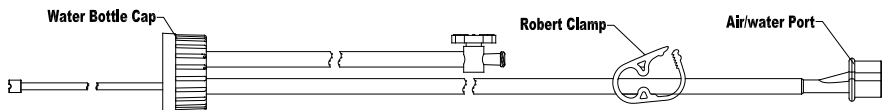
Instructions for Use



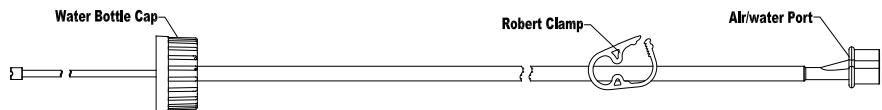
SEN-IT



SEN-IT-O-H2 / SEN-IT-F-H2



SEN-INT-O-CO2 / SEN-INT-F-CO2



SEN-INT-O / SEN-INT-F

ENGLISH

Caution: US federal law restricts use of this device to sale by or on the order of a physician (or properly licensed practitioner).

INTENDED USE

This device (tubing and accessories to accommodate various GI endoscopes and irrigation pumps) is intended to provide irrigation via sterile water and to supply air (via an air pump) or CO₂ (via a CO₂ pump) along with sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump or electrosurgical unit.

DEVICE DESCRIPTION

It serves as an alternative to the reusable water bottle in GI Endoscopy. The tubing design minimizes infection control risks that are associated with manual cleaning and sterilization. The following devices are included in this IFU:

RPN	DESCRIPTION	
SEN-IT	Irrigation Tubing	Provide irrigation via sterile water to the water jet channel
SEN-IT-O-H2	Hybrid Tubing	Provide irrigation via sterile water and to supply air (via an air pump) or CO ₂ (via a CO ₂ pump)
SEN-IT-F-H2		
SEN-INT-O-CO2	Insufflation Tubing with CO ₂	Supply water, air (via an air pump) and CO ₂ (via a CO ₂ pump) to the air/water channel
SEN-INT-F-CO2		
SEN-INT-O	Insufflation Tubing	Supply water and air (via an air pump) to the air/water channel
SEN-INT-F		

MATERIAL

This device does not contain latex, phthalates, or animal derivatives.

CONTRAINDICATIONS

Contraindications include those specific to any endoscopic procedure.

WARNINGS

Please read all instructions before using this device.

Check the expiration date; do not use if expired.

Inspect the package for shipping or handling damage. If damage is evident, do not use. Please notify Cook Medical for return authorization.

Tubing is for 24 hours use (discard daily).

If water bottle needs to be replaced, use proper aseptic technique.

NEVER attach or reattach the tubing to an endoscope that is/was inside the patient and has not been reprocessed.

ALWAYS close the Robert clamp before disconnecting the tubing from the endoscope.

ALWAYS inspect the endoscope's O-rings and rubbers (air/ water valve, endoscope connection, etc.) for damage. Damaged components can result in less-than-optimal performance of the tubing.

The following WARNINGS are only applicable for Hybrid Tubing (SEN-IT-O-H2, SEN-IT-F-H2), Insufflation Tubing with CO₂ (SEN-INT-O-CO₂, SEN-INT-F-CO₂), Insufflation Tubing (SEN-INT-O, and SEN-INT-F):

ALWAYS prime the air/ water channel prior to inserting the endoscope into the patient.

NEVER turn off the air processor/ CO₂ while the tubing is attached to an endoscope.

The following WARNINGS are only applicable for Hybrid Tubing (SEN-IT-O-H2, SEN-IT-F-H2), and Irrigation Tubing (SEN-IT):

ALWAYS prime the auxiliary water channel prior to inserting the GI endoscope into patient.

If any of the above warnings are not followed, or there is any reason to believe that the device was contaminated, immediately discard the entire tubing and water bottle. Replace with a new tubing and unopened sterile water bottle.

PRECAUTIONS

If a sterile water bottle needs replacing during a procedure, refrain from depressing the air/water valve. There is a potential for backflow to occur if the air/ water valve is depressed while no sterile water bottle is connected to the tubing. If this occurs, replace the tube immediately.

Sterility is guaranteed unless the sterile pouch is damaged, or the seal is broken.

Do not store in direct sunlight, at extreme temperature, or in high humidity.

Re-use may cause cross-infection.

PACKAGING AND STERILIZATION

This device is packaged and sterilized with ethylene oxide. It cannot be re-sterilized.

Validity of sterilization: 3 years

USER QUALIFICATIONS

This device should only be used by or under the supervision of physicians who have been trained in endoscopic procedures.

FREQUENCY OF USE

This device is rated for 24-hour, multi-patient use. Discard daily.

WARNINGS

The maximum number of patients is up to 15 patients in 24 hours, and the maximum duration of use shall not exceed 15-hours in a 24-hour period. The check valve attached to the irrigation tubing shall be replaced after every patient use.

INSTRUCTIONS FOR USE

Open the sterile peel pack and remove the tubing. Open a bottle of sterile water (1000cc or 1500cc). Drop the weighted tube into the sterile water bottle and firmly tighten the bottle cap to ensure a secure seal. Remove the 24hr label from the pouch and apply it to the bottle of sterile water. Write the date and time on the label.

1. Place the tubing connected to the bottle of sterile water in the water bottle holder provided on the pump.

The following instructions are only applicable for Hybrid Tubing (SEN-IT-O-H2, SEN-IT-F-H2), Insufflation Tubing with CO₂ (SEN-INT-O-CO₂, SEN-INT-F-CO₂), and Insufflation Tubing (SEN-INT-O, SEN-INT-F).

2. Connect the air/water valve of the tubing to the air/water port of the GI endoscope with a firm pushing motion. If using a CO₂ source, connect the CO₂ insert of the tubing directly to the CO₂ source. Follow instructions from the CO₂ source manufacturer.
3. Turn on the air processor or CO₂ source.

4. Prime the channel and test for air and water prior to insertion of endoscope. If the water pressure is low, then ensure that the water bottle is tightly closed.

WARNINGS

If the water bottle needs to be replaced, use proper aseptic technique.

6. Turn off the air processor or CO₂ source at the conclusion of the procedure
7. When the procedure is finished, close the pinch clip, or Robert clamp, and disconnect the Cap from endoscope.
8. Discard the Cap daily.

The following instructions are only applicable for Hybrid Tubing (SEN-IT-O-H2, SEN-IT-F-H2), and Irrigation Tubing (SEN-IT).

NOTE: To prevent water leakage, place the tubing in the pump head regardless of whether irrigation is needed.

2. Holding both connectors in one hand, open the pump head, insert the pump tube of the clean connecting tube and close the pump head. (Note: Ensure that the pump tubing between the tubing connectors is centered, aligned, and carefully pulled taut before closing the pump head.) Take care to prevent the connectors from touching the ground.
3. Attach the Auxiliary Water Jet Connector on the tubing to the GI endoscope's auxiliary water port by engaging the threads and turning slowly until you feel resistance. (For specific instructions with regards to the Auxiliary Water Jet Connector, follow the IFU for the connector).
4. Prime the tubing and the auxiliary water channel prior to use by activating the foot pedal; flush water through the entire GI endoscope.

WARNINGS

To prevent cross-contamination, always prime the auxiliary water channel prior to inserting the GI endoscope into the patient.

5. Turn off the pump at the conclusion of the procedure
6. When the procedure is finished, close the pinch clip, or Robert clamp, and disconnect the Cap from endoscope.
7. Discard daily.

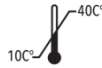
STORAGE AND TRANSPORTATION

Store at room temperature between 50 °F and 104 °F (10°C and 40°C), away from sunlight, non-corrosive gases, and in a well-ventilated area.

DEVICE DISPOSAL

After use, this device may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

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

	Manufacturer		Keep dry
	Temperature limit		Keep away from sunlight
	Country of manufacture		Medical device
	Use by date		For Single use only.
	Batch number		Caution
	Sterilized using ethylene oxide		Single sterile barrier system
	Do not use product if package is damaged		DEHP free
	Do not re-sterilize		Consult instructions for use
	Number of devices in package		Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Not made with natural rubber latex		Model Number
	Catalogue number		Distributor
	Unique device identifier		



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