

COOK®

MEDICAL

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Sentrus™ Endoscopic Bedside Kit

Instructions for Use

ENGLISH

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

DEVICE DESCRIPTION

Endoscopic Bedside Kit may contain the following:

- Gauze
- Sentrus™ Medical Lubricating Jelly (18g)
- Sentrus™ Cleaning Sponge with 3E Cleaner Detergent
- 850mL Plastic Tray
- Sentrus™ Endoscope
- Transport Bag
- Biohazard Label
- Sentrus™ Dual-End Cleaning Brush
- Sentrus™ Endoscopy Adapter Set
- Sentrus™ Suction Tube

INTENDED USES

These devices are intended to be used for the preparation of an endoscope prior to an endoscopic procedure and pre-cleaning of an endoscope after a procedure.

COMPONENT DEVICE	INTENDED USE	
Gauze	This device is intended to be used together with medical lubricating jelly; put the lubricating jelly on the Gauze, then lubricate the endoscope.	
Sentrus™ Medical Lubricating Jelly (18g)	This device is a sterile, water-soluble, latex-free gel intended for the smooth insertion of endoscope, reducing the risk of trauma during procedures.	
Sentrus™ Endoscopy Adapter Set	Biopsy Valve	This device is intended to be fitted to an endoscope biopsy port to prevent leakage of gases and body fluids during an endoscopic procedure.
	Air/Water Valve	This device is intended to be fitted to an endoscope air/water channel to

		control the inflow of medical gases and water, whilst preventing back-flow.
	Suction Valve	This device is intended to be fitted to an endoscope suction channel to control the operations of suction, whilst preventing inflow of air.
	Cleaning Adapter	This device is used to flush liquid into the air/water channel after using rigid or flexible endoscope, before or after mechanical cleaning.
	Auxiliary Water Jet Connector	This device is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.
Sentrus™ Endoscope Transport Bag	This device is intended to provide safe and easy transportation of an endoscope from the procedure room to the reprocessing room after the endoscopy.	
Tray	This product is used at the bedside for endoscope cleaning, then placed over the scope tip to protect the tip during transportation.	
Sentrus™ Cleaning Sponge		
Sentrus™ Suction Tube	This device is intended to connect the endoscope with a suction pump (e.g. Ardo Senator 30 suction pump) to provide suction during endoscopic procedures. This device is designed for 24-hour, multi-patient use to minimize infection control risks associated with reuse.	
Biohazard Label	This label is used to warn that the medical device may contain biohazardous substances or has been in contact with biohazard sources, reminding people to take corresponding protective measures and follow specific operation specifications when handling, using or disposing of it, so as to prevent	

	the leakage and spread of biohazardous substances, and avoid harm to human health and the environment.
Sentrus™ Dual-end Cleaning Brush	This device is intended for mechanical pre-cleaning of the endoscope channels, valves and valve shafts.

MATERIAL

These devices do not contain latex, phthalates, or animal derivatives.

The 3E Cleaner Detergent contains: Amylase, alpha - Lipase (Triacylglycerol), Subtilisin. May produce an allergic reaction.

CONTRAINDICATIONS

Do not use if sensitive or allergic to any of the device ingredients.

Patients with deep wounds or open ulcers, bleeding, and irritating mucosa are prohibited from using it.

Contraindications include those specific to any endoscopic procedure.

USER QUALIFICATIONS

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

WARNINGS

General Warnings

- Please read all instructions before using these devices.
- Follow society guidelines and original equipment manufacturer recommendations to properly prepare for an endoscopy procedure and pre-clean the endoscope after an endoscopy procedure.
- These devices are designed for single use only. Attempts to reprocess and/or reuse may lead to device failure and/or transmission of disease.
- Use appropriate infection control principles and wear appropriate personal protective equipment (PPE). Appropriate PPE may include; eye wear, a face mask, moisture-resistant clothing and chemical resistant gloves that fit properly and are long enough so that skin is not exposed. Otherwise, blood, mucous and other potentially infections material from the patient could pose an infection control risk.
- Inspect all packaging for shipping or handling damage. If damage is

evident, do not use. Please notify Cook Medical for return authorization.

- Check the expiration date; do not use if expired.

Device Specific Warnings

Sentrus™ Cleaning Sponge and 3E Cleaner Detergent

- 3E Cleaner Detergent is harmful if swallowed and irritating to eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Avoid contact with skin.
- Wear suitable gloves and eye/face protection.
- Sentrus™ Medical Lubricating Jelly (18g)
- This device is limited to entry through the orifices of the human body.
- This device is used with other endoscopic medical devices such as an endoscope.
- Sterile Lubricant may affect sample detection accuracy.
- Do not use if the lubricant has lumps.
- Use one device at a time; more than one device per procedure may result in unclear risks and adverse side effects.
- This device is only suitable for intact mucosa and cannot be used on damaged mucosa or injured skin.
- If irritation or discomfort occurs, discontinue use and consult a physician. Keep out of eyes and ears. Keep out of the reach of children.
- If contact with eyes occurs, flush eyes with plenty of 0.9% physiological saline solution. If no saline is available, flush with copious amounts of water.

Sentrus™ Endoscopy Adapter Set

ADAPTER SET COMPONENT	WARNINGS
Air/Water Valve and Suction Valve	Make sure the holes in the air/water and suction valves are not clogged or blocked. (This could cause continuous air/CO ₂ flow, or inadequate suction.)
Biopsy Valve	Do not use a sharp or pointed object to prime the valve prior to use. Do not leave a device hanging from the valve. Doing so can cause the creation of a larger valve slit/hole that may cause leakage.

	If the lid of the valve is opened while attached to the endoscope during a procedure, scope suction will be compromised and leakage may occur. If leakage occurs, a sterile gauze should be used to cover the valve.
Auxiliary Water Jet Connector	Never attach or reattach the Auxiliary Water Jet Connector to an endoscope that is/was inside the patient and has not been reprocessed. Exposure to bodily fluids may occur during the connection or disconnection of this device. The User is responsible for adhering to Body Substance Isolation protocols. Do not insert this device into the patient. The device should be attached to the auxiliary water port of a flexible gastrointestinal endoscope and an irrigation source. Use proper techniques to avoid risk of aspiration of a patient. Always prime the auxiliary water channel or biopsy channel prior to inserting the endoscope into the patient.
Cleaning Adapter	Don't use during patient procedures in place of standard air/water valve for insufflation and lens washing.

Sentrus™ Dual-End Cleaning Brush

- Original Equipment Manufacturer's guidelines regarding the care and cleaning of individual endoscope features must be reviewed prior to the use of any cleaning brush.
- Ensure the brush is intact before use, do not use if it is damaged or has loose bristles.
- Do not apply excessive force with the bristles to avoid damaging the surface of the endoscope.
- Take care to prevent the bristles from falling out or loosening during cleaning to avoid contaminating the cleaning equipment.

- If the brush bristles fall out, deform, or suffer other damage during use, stop using the brush immediately and replace it with a new one.
- Never transfer a used cleaning brush from one endoscope to another endoscope, since cross-contamination could occur and result in patient complications. Dual-End Cleaning Brushes are designed to safely remove debris, some of which can be retained in the bristle structure.
- Do not use the Dual-End Cleaning Brush in a specific channel if use is not recommended by the endoscope's Original Equipment Manufacturer.

POTENTIAL COMPLICATIONS

Irritation or allergic reaction to ingredients of the 3E Cleaner Detergent.

Infection resulting from cross-contamination.

PACKAGING AND STERILIZATION

The Sentrus Medical Lubricating jelly is irradiation sterilized. It cannot be re-sterilized.

The Sentrus Endoscopy Adapter Set is sterilized with ethylene oxide. It cannot be re-sterilized.

The validity of device sterilization lasts 2 years.

INSTRUCTIONS FOR USE

1. Open package to remove and separate its contents.
2. Unfold the *Sentrus*™ Transport Bag to cover the endoscope cart/work surface.
3. Separate all the articles and leave the wrapped *Sentrus*™ Cleaning Sponge in its package until the endoscope is ready to be pre-cleaned.
4. Place the Biohazard label in a dry location.

Device specific instructions for use

Sentrus™ Medical Lubricating Jelly and Gauze:

It is recommended to wash or disinfect your hands before and after use.

1. Visually inspect the pouch or tube to detect any abnormality. Do not use if pouch is damaged or opened.
2. Tear sachet at one end and squeeze Lubrication Jelly on the Gauze as needed

and then lubricate the endoscope.

Sentrus™ Endoscopy Adapter Set:

COMPONENT DEVICE	INSTRUCTIONS FOR USE
Suction Valve	1. Remove the suction valve from the tray. 2. Insert the suction valve into suction cylinder of an endoscope. 3. Twist valve slightly to seat in proper orientation within the cylinder. 4. Confirm that the valve fits securely and that there is no gap between the valve end cap and the endoscope. WARNINGS The valve should not be able to be rotated once it is fully inserted into the cylinder. 5. Actuate the valve by pressing and releasing a few times to confirm smooth function. Note: Dipping in water may facilitate ease of use.
Air/Water Valve	1. Remove the Air/Water Valve from the tray. 2. Insert the Air/Water Valve into the air/water cylinder of an endoscope. 3. Confirm that the valve fits securely and that there is no gap between the valve end cap and the endoscope. 4. Actuate the valve by pressing and releasing a few times to confirm smooth function. Note: Dipping in water may facilitate ease of use.
Biopsy Valve	1. Remove the device from the tray. 2. Securely place the Biopsy Valve onto the

	biopsy/suction channel opening of the endoscope. Note: This Biopsy Valve does not accommodate a luer-lock syringe without an irrigating adapter.
Auxiliary Water Jet Connector	1. Remove the device from the tray. 2. Attach the Auxiliary Water Jet Connector to the endoscope by screwing it onto the auxiliary water port. WARNINGS Take care to ensure that the scope connector is aligned to the port and avoid excessive tightening. Misalignment or excessive tightening of the scope connector could lead to the possibility of leakage. 3. Once the Auxiliary Water Jet Connector is attached to the auxiliary water port of the endoscope, attach irrigation tubing to the Auxiliary Water Jet Connector. The Auxiliary Water Jet Connector is manufactured with a one-way valve to minimize the risk of cross-contamination of the irrigation system. 4. Place distal tip of endoscope into water filled receptacle, press and hold the Suction Valve for 2-3 seconds and then release to confirm the endoscope is suctioning water. 5. With distal tip of scope still under water, rest finger over hole in Air/Water Valve to confirm that air is exiting the tip of scope, which is evident by the production of air bubbles. 6. Remove distal tip of endoscope from water filled receptacle. 7. Press the Air/Water Valve and hold for 5-10 seconds to confirm that water exits the air/water nozzle on the end of the endoscope.
Cleaning	1. Remove the device from the tray.

Adapter	2. Turn off the airflow regulator on the light source after initial rinsing of scope (per facility guidelines). 3. Remove the Air/Water valve from air/water cylinder and insert the Cleaning Adapter into the air/water cylinder on endoscope handle. 4. Place the distal end of the endoscope into a basin of water. 5. On the light source, turn on the airflow regulator and set it to a maximum output. 6. Depress the Cleaning Adapter for the recommended time per the endoscope manufacturer's reprocessing instructions. Note: This step flushes the air/water channel with water. 7. Release the Cleaning Adapter while keeping the distal end of the endoscope in the basin of water. 8. Flush air for the recommended time per the endoscope manufacturer's reprocessing instructions. Note: This step will produce air bubbles in the basin of water. 9. Turn off the air/flow regulator on the light source. 10. Remove distal end of endoscope from basin of water. 11. Remove the Cleaning Adapter from endoscope after precleaning step is completed and discard in accordance with institutional guidelines.
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Sentrus™ Suction Tubing

1. Open the package and remove the Sentrus Suction Tubing
2. Connect the Sentrus Suction Tubing to the endoscope and to the disposable secretion bag or the reusable collection container provided for this purpose.

Sentrus™ Cleaning Sponge with 3E Cleaner

1. Before using the Bedside Cleaning Sponge, have the following available:
 - Personal Protective Equipment (PPE) – When handling cleaning agents and/or disinfectants, PPE is always required. PPE includes gloves, eye protection, impervious gown, face shield or simple surgical mask.



- A plastic container for detergent (if product does not include a plastic container).
2. Open package to remove sponge.
 3. Put the sponge in the plastic container and fill with 500ml of water. Squeeze the sponge 5-7 times to prepare the 3E Cleaner Detergent.
 4. Place sponge around the insertion tube of scope or tubular instrument.
 5. Run sponge down length of scope or instrument to remove gross soil.
 6. Rinse sponge and repeat until surface is clean.
 7. Put sponge around the distal tip of endoscope during transportation.
 8. Discard sponge and plastic container.

Sentrus™ Dual-End Cleaning Brush

- *Cleaning endoscope channel:*
1. Check the cleaning brush before use. Brush tube and head should have no folds, breakage, or damage.
 2. Insert the Channel cleaning brush (small brush) into the endoscope channel and push it slowly to clean the channel until the cleaning brush is pushed out from the other end of the channel. Do not force too hard and rotate the cleaning brush at will when pushing to prevent damage to the channel.
 3. Slowly pull the cleaning brush out of the channel.

Note: Suitable cleaning medium can be used during cleaning.

- *Cleaning endoscope valve and valve shafts:*
1. Check the cleaning brush before use. Brush head should have no damage.
 2. Grip the handle and insert the Channel-opening cleaning brush (large

brush) into the endoscope valve; push and pull it slowly to clean the valve. Do not force too much and rotate the cleaning brush at will when pushing and pulling to prevent damage to the valve.

Note: Suitable cleaning medium can be used during cleaning.

Sentrus™ Endoscope Transport Bag

1. When finished pre-cleaning and disconnecting the endoscope per manufacturer's recommendations, gently lay the endoscope, centered on the Endoscope Transport Bag.
2. Carefully fold the sides (left and right) of the Endoscope Transport Bag over the endoscope and pull gently on the drawstrings to close the Endoscope Transport Bag, fully covering the endoscope.
3. Place the Biohazard Label on the exterior of the Endoscope Transport Bag by removing its paper backing and adhering it directly to the Endoscope Transport Bag.

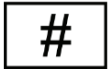
STORAGE AND TRANSPORTATION

Store at room temperature between 55 °F and 77 °F (10°C and 25°C), away from sunlight, non-corrosive gases, and in a well-ventilated area.

DEVICE DISPOSAL

After use, these devices may be potential biohazards. 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
	Single sterile barrier system		Sterilized using ethylene oxide
	Non-sterile		Sterilized using irradiation
	Do not use product if package is damaged		Not made with natural rubber latex
	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.
	DEHP free		Model Number



Distributor

REF

Catalogue number

UDI

Unique device identifier



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