

File No.	Version / Revision No	Effective Date
AMK-SM-008	2/2	2020.6.11



Instructions for Use



1.Product name: Disposable closed suction catheter - 72 Hours

2.Product model:Child type (6Fr, 8Fr) and Adult type (10Fr, 12Fr, 14Fr, 16Fr).

3. Product performance:

- The product is made of high quality medical PVC.
- Soft Blue tip design reduces irritation and damage to the tracheal mucosa.
- The product uses several closed designs and additional cleaning function. It can effectively avoid the risk of caregiver being infected by the air exhaled by the patient during the treatment process.
- In clinical use, the flushing port with a one-way valve design to prevent liquid reflux after flushing.
- This design makes the Closed Suction Catheter tube more convenient, safety and easier to operate by caregiver.
- The black indicator line indicates the position of the withdrawal suction tube to avoid the ETT airway block.
- Closed Suction Catheter should be free of sensitization and mucosal irritation, the Cytotoxicity is not more than level 2. The products will sterilization by EO.

4. Main product structures:

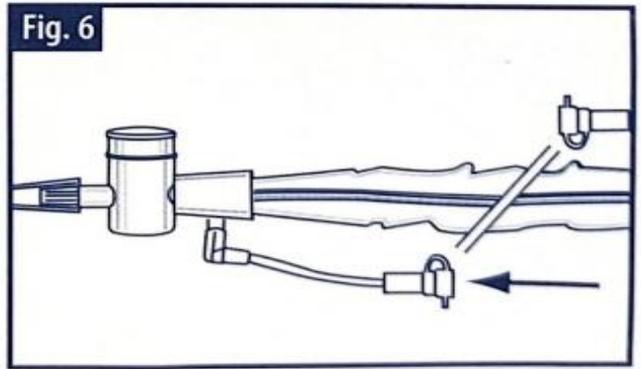
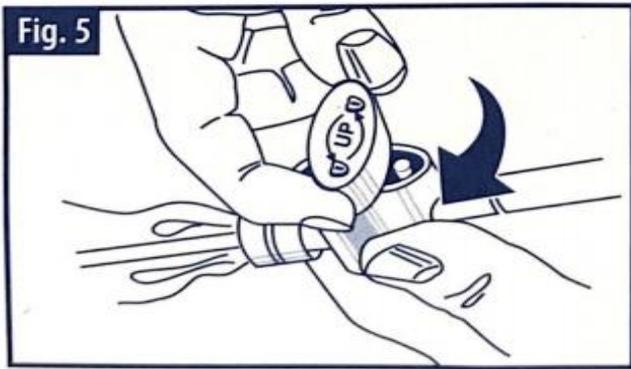
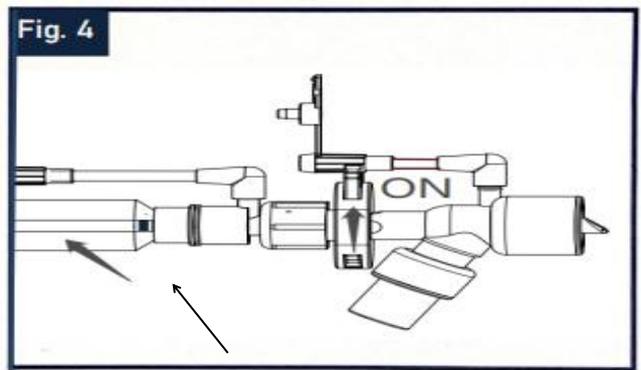
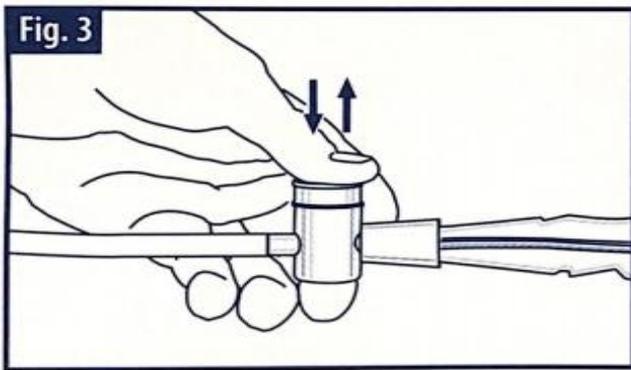
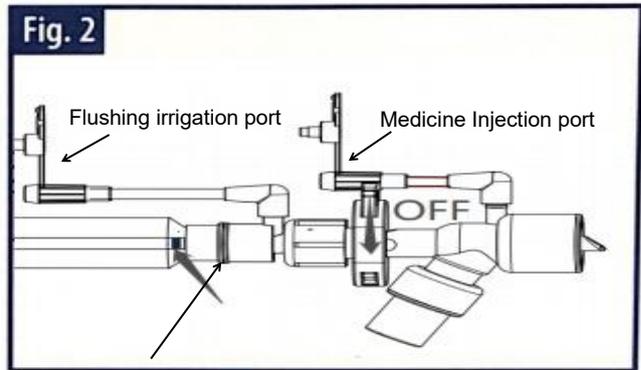
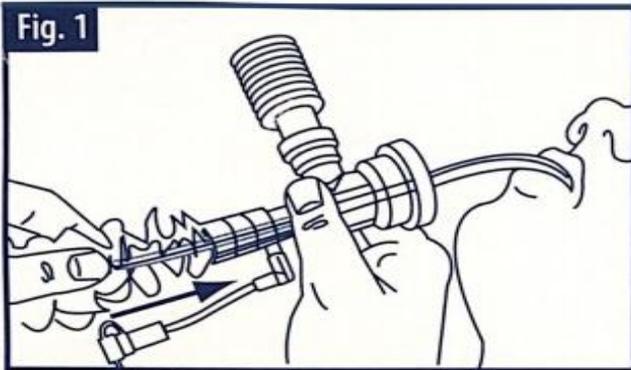
The main parts include Y-piece Double Swivel Elbow Connector, Transfer connector, Flex catheter mount, double-position Push Switch, PU Sleeve cover, PVC Suction Catheter, Flushing irrigation port, Medicine Injection port, Negative pressure thumb control valve, Suction Tube Connector and so on.

5. Product scope:

It is suitable for respiratory system diseases, general anesthesia, surgical treatment, and endotracheal tube (or tracheostomy tube) emergency rescue. When it is used for artificial ventilator support, it can extract the secretions of the respiratory tract of patients.

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6. Instructions for use:



Setup:

1. Select appropriate size catheter.
2. Attach thumb control valve to suction tubing.
3. Depress and hold thumb valve and simultaneously adjust vacuum regulator to desired level.
4. Release thumb control valve and attach catheter between patient and the ventilator circuit.
5. Connect patient end connector with ET Tube (Or Tracheotomy tube), Connect ventilator end connector with Breathing tube Catheter mount for breathing. Connect negative pressure end connector with Suction line.

Suggested Suction Procedure:

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1. Stabilize catheter and endotracheal (ET) adapter with one hand then push the catheter into the endotracheal tube with the thumb and forefinger of the opposite hand (Fig 1)
2. Advance catheter to desired depth.
3. Depress and hold thumb control valve, then gently withdraw catheter. Stop withdrawal when black marking ring is visible inside sleeve (Fig 2)
4. Release thumb control valve and turn off the switch.
5. Instill desired amount of fluid by syringe (Other Flush infusion set) into the irrigation port. Depress and hold thumb control valve while flushing. (10mls 0.9% saline flush is recommended to use) .
6. After flushing the tube tip, remove syringe and close the cap on the irrigation port. (For more detail, please see *Catheter Irrigation Instruction* as follow)
7. Repeat steps 1 through 6 above as necessary.
8. It is mandatory to replace the closed suction catheter 72 hours. Change more frequently if catheter becomes heavily soiled during use.
9. The maximum sputum suction pressure for adults does not exceed 150mmHg, and the sputum suction pressure for infants and children is 80-100mmHg. The actual sputum suction time is recommended not to exceed 15s.

Patient Lavage Instructions:

1. For intubated patient, advance catheter 10-13cm (4-5 inches) into the endotracheal Tube. For tracheostomy patient, advance the catheter 3-4 cm (1.5-2 inches) into the tracheostomy tube.
2. Advance catheter to desired depth and follow the above suggested suction procedure.

Catheter Irrigation Instruction:

1. Be sure the black marking ring is visible in the sleeve (Fig 2). Be sure push off switch (Fig 2). Open cap on irrigation port.
2. Insert syringe into irrigation port and release your hand.
3. Depress the thumb control valve (Fig 3) until the catheter and chamber are clear (Fig 4).
4. Remove syringe and close cap on the irrigation port.
5. Lift and turn thumb control valve 180 degrees to lock position (Fig 5)
6. Place catheter and suction tubing alongside breathing circuit.

Tracheostomy Patients:

1. Use tracheostomy 30 cm (12 inch) catheters for patients with tracheostomy artificial airway only. If 30 cm catheter is used on endotracheal artificial airway, ineffective suction may result.
2. Do not use 60 cm (23.6 inch) catheters on tracheostomy patients. Mucosal damage may result.

Control Depth Suction (For catheters with numerical markings only)

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1. Align any printed depth number on the catheter with the similar number printed on the endotracheal tube, or observe the printed number on the endotracheal tube closest to the endotracheal tube adapter.
2. Add 6 cm to this number.
3. Advance catheter until the sum (depth plus 6) appears in the window directly across from irrigation port connector.
4. Catheter tip will be within 1 cm of the end of the artificial airway.

Thumb Control Valve Operation:

1. The thumb control valve can be locked to prevent inadvertent or accidental suction. To lock, lift white part of thumb control valve and rotate 180 degrees. To unlock, repeat this action (Fig 5).

Day Sticker Usage:

1. Closed Suction Systems are mandatory for 72 hours use to decrease the potential for nosocomial infections.
2. Apply the appropriate day sticker to the thumb control valve. Example: If Suction system is opened on Monday, place the Thursday sticker on thumb control valve.

Warning:

1. Do not trim or cut the endotracheal tube (not supplied) while the closed Suction Catheter is attached, otherwise the catheter may also be cut and that portion of the catheter maybe aspirated into the lower respiratory tract of the patient and may cause death or serious injury.
2. Do not reuse, reprocess, or resterilize this medical device. Reuse, reprocessing, or resterilization may a) adversely affect the known biocompatibility characteristics of the device, b) compromise the structural integrity of the device, c) lead to the device not performing as intended, or d) create a risk of contamination and cause the transmission of infections diseases resulting in patient injury, illness, or death.

Cautions:

- (1) Inspect Closed Suction Catheter package before opening. Do not use product if packaging has been compromised. Non-sterile contents may cause infection.
- (2) Single patient use only.
- (3) Closed Suction systems are mandatory to replace the closed suction catheter 72 hours. Change more frequently if catheter becomes heavily soiled during use.
- (4) Do not use 60 cm (23.6 inch) catheters on tracheostomy patients. Mucosal damage may result.
- (5) Select the appropriate size catheter. Most experts suggest that the catheter selected should occupy no more than one half of the internal diameter of the artificial airway.

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- (6) Do not leave the catheter within the airway. Always pull back until the black stripe is visible within the sleeve. Any catheter left extended into the airway will cause increased airway resistance.
- (7) Use appropriate regulated vacuum levels. Most experts suggest -80 to -120 mm/Hg (-10.7 to -15.9 kPa)
- (8) Use appropriate suction technique. Most experts suggest that the entire suction procedure should last no longer than 10 to 15 seconds and that actual duration of negative pressure should be no longer than 5 to 8 seconds per episode.
- (9) Always use caution and good clinical judgement no matter what ventilator mode is in use. If the clinician notes any signs of suction intolerance such as oxygen desaturation, negative ventilator system pressures, patient stress or excessive discomfort, adjustments to the ventilator settings may need to be made. These adjustments (please refer to the ventilator's instructions for use) may include manipulation of the inspiratory trigger sensitivity, inspiratory volume or flowrate, and selection of a different ventilator mode; or may require the use of an alternate suction technique. Failure to follow the above precautions may increase the risk of positive and negative barotrauma.
- (10) Always place the thumb valve in the locked position when not in use to prevent inadvertent activation.

9. Identification:

Item	Symbol	Instruction
Single use		Explain that the product cannot be used again
Caution		Remind users of matters needing attention
Ethylene oxide sterilization		Represents products sterilized with ethylene oxide
LATEX FREE		This product does not contain latex

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Do not use if the packaging is damaged		Remind users that the package is damaged and cannot be used
Keep dry		Remind users to save matters that should be noted

Storage conditions:

Packaged closed suction catheter should be stored in a room with a humidity of not more than 80%, no corrosive gas, and a well-ventilated room.

Shelf life:

Packaged Closed Suction Catheter, storage and transport in compliance with the rules, the self-life will be 5 years since the sterilization date.



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