

Deluxe

Closed Suction System for Adults

General Instructions for Use

Intended Use

Sunset Deluxe Closed Suction System is intended for endotracheal or tracheostomy suction of ventilator dependent adult patients. It is operated by health professionals in medical institutions for single patient use.

- Recommended period of use is 24 hours or if visibly soiled or faulty. Defer to institutional policy/guidelines for changeout indications.
- For the series used with tracheostomy tubes, the length of catheter is 305mm and is indicated on the pack.




Product Description

Sunset Deluxe Closed Suction System consists of 3 essential parts: a suction catheter with a protective sleeve, a vacuum control device and a patient end adaptor with a flushing system. The device connects between the breathing circuit and the artificial airway for simultaneous suction and ventilation. There are different catheter lengths of the device, one for endotracheal tube and one for tracheostomy tube, and it can be with or without a MDI port.

Contraindications

The device intends to suck the secretions from the patients with artificial airways. The pulmonary secretions from a patient's artificial airways should be removed to prevent its obstruction, otherwise, they cause the patient's death or to be lethal. Therefore, there is no absolute contraindication to the closed suction system.

Size

Product Code	Catheter Length	Remark	Outer Diameter	Packaging	ISO Color
VEN160100A / VEN160100AM	540mm	Endotracheal	10FR / 3.33 mm	20ea/box	
VEN162100A / VEN162100AM		Tracheostomy			
VEN161100A / VEN161100AM	305mm	Tracheostomy			
VEN163100A / VEN163100AM		Endotracheal			
VEN160120 / VEN160120M	540mm	Endotracheal	12FR / 4.0 mm	20ea/box	
VEN162120 / VEN162120M		Tracheostomy			
VEN161120 / VEN161120M	305mm	Tracheostomy			
VEN163120 / VEN163120M		Endotracheal			
VEN160140 / VEN160140M	540mm	Endotracheal	14FR / 4.67 mm	20ea/box	
VEN162140 / VEN162140M		Tracheostomy			
VEN161140 / VEN161140M	305mm	Tracheostomy			
VEN163140 / VEN163140M		Endotracheal			
VEN160160 / VEN160160M	540mm	Endotracheal	16FR / 5.3 mm	20ea/box	
VEN162160 / VEN162160M		Tracheostomy			
VEN161160 / VEN161160M	305mm	Tracheostomy			
VEN163160 / VEN163160M		Endotracheal			

- M = with MDI port

Symbol



EN / Caution



EN / Sterilized using ethylene oxide



EN / Contains or presence of phthalate-DINP



EN / Does not contain natural rubber latex



EN / Do not use if package is damaged



EN / Do not reuse



EN / Do not resterilise



EN / Do not use in MRI



EN / Consult instructions for use



EN / Temperature limitation
Upper limit: 49°C
Lower limit: 5°C



EN / Sale by or on the order of a physician



EN / Manufacturer



EN / Date of manufacture



EN / Catalog number



EN / Batch code



EN / Use by date



EN / Keep dry



EN / Keep away from sunlight

Warning

1. Do not use endotracheal length catheter in patient with tracheostomy tube. The extra length may cause mucosal tissue injured. Do not use tracheostomy length catheters for endotracheal tubes. The short length will result in insufficient suctioning.
2. This is single use product. Do not reuse or resterilize this device. Reuse and resterilization may lead to the device not performing as intended, malfunction or create a risk of cross infection.
3. Do not CUT endotracheal tube while Closed Suction System is attached. Otherwise, the suction catheter may be cut and the cut portion of catheter may be aspirated into lower respiratory tract.

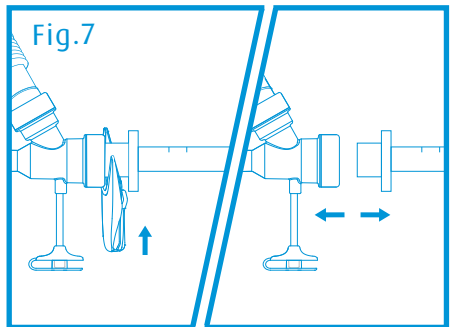
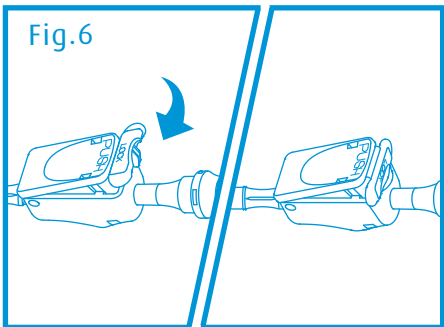
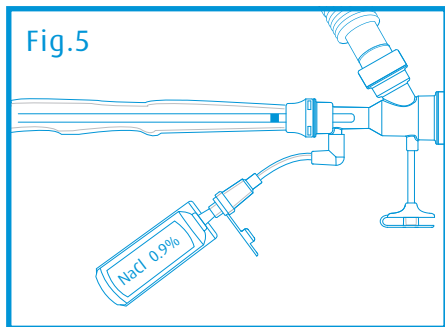
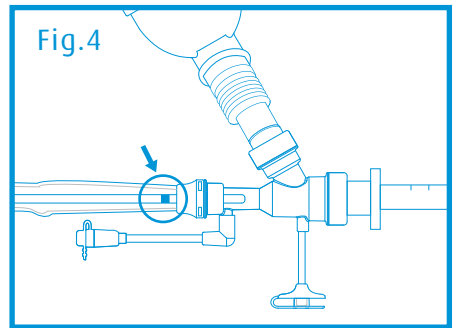
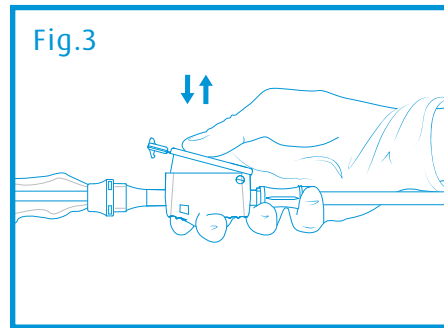
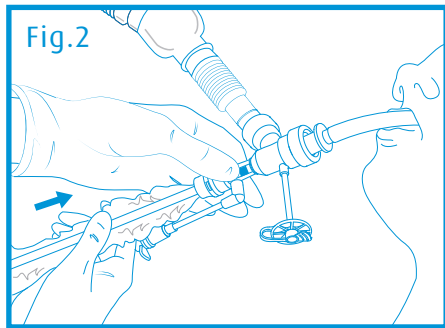
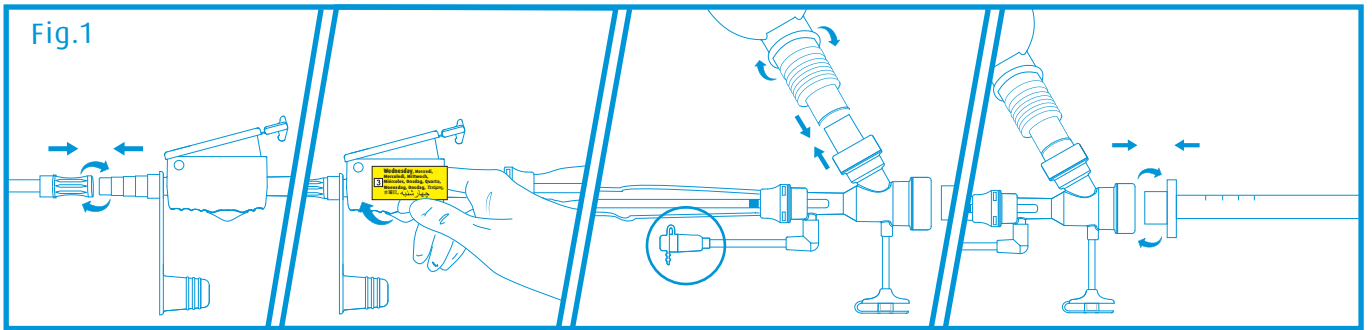
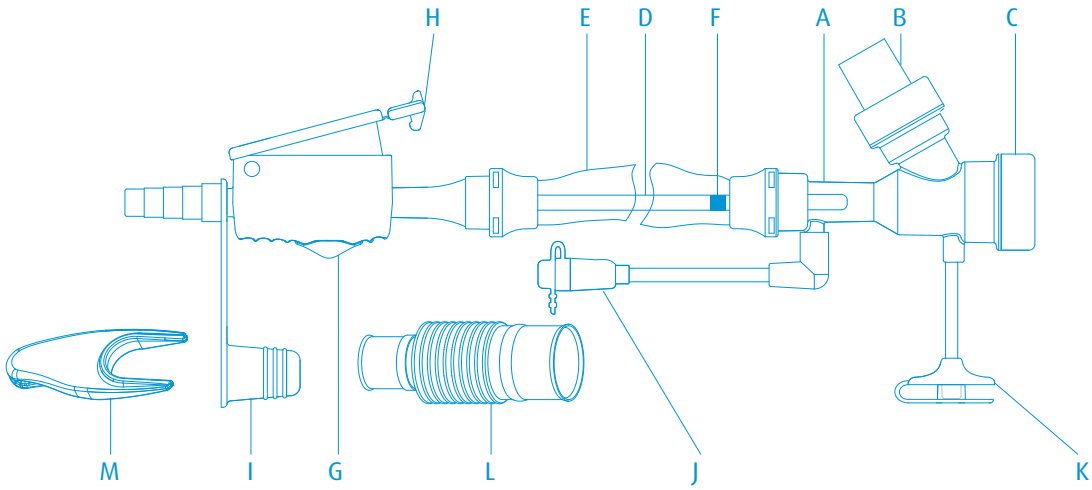
Caution

1. Check the product package before use. Do not use if product packaging has been damaged.
2. Withdraw suction catheter from the patients until the black marking can be seen on the distal side of patient-end adaptor.
3. Do not pull suction catheter out of patient-end adaptor.
4. The product should be handled by trained and qualified clinicians.
5. Rx Only – Federal law restricts this device to sale by or on the order of a physician.
6. For series used with tracheostomy tubes, the length of catheter is 305mm and is indicated on the pack.
7. Do not leave catheter within the airway, it will cause increased airway resistance.
8. Always place the vacuum control device in the locked position when not in use.
9. Recommended vacuum settings 80 to 120mm/Hg.
10. The entire suction procedure should last no longer than 10 to 15 seconds.
11. When used in conjunction with other manufacture's products always refer to their instruction for use.
12. Excess fluid in heat and moisture exchangers (HMEs) or heat moisture exchanging filters (HMEFs) may increase resistance to flow. Follow manufacturer's instructions and replace HME(F).

Pre-Use Check

- There are no standard connections for suction tubing, hospitals should qualify the tubing fits the series of Sunset Deluxe Closed Suction Systems.
- Inspect the package before opening. Ensure the product has not been compromised.
- Select the appropriate catheter length and size following clinical guideline. It is recommended that the catheter size is no more than half the size of patient's artificial airway.

Suggested Suction Procedure



Suggested Suction Procedure

1. **(Fig. 1)** Attach suction tubing to the connector on the vacuum control device (G) . Connect suction tubing to the hospital vacuum system.
2. **(Fig. 1)** Attach a day label stick to the vacuum control device indicating the date of use.
3. **(Fig. 1)** Attach the 15 mm male connector of the patient end adaptor (B) to the breathing system (machine-end); the 15 mm female connector (C) to the patient's artificial airway (patient-end) .
4. **(Fig. 1)** The included corrugated connector (L) may be attached between the 15 mm male connector (B) and the breathing system if needed.
5. **(Fig. 2)** Unlock the cover of the vacuum control device(H).
6. **(Fig. 2)** Hold the patient end adaptor with one hand. Carefully advance the catheter down the airway with the other hand.
7. Advance catheter(D)to desired depth. For endotracheal tube type, line up the marking numbers. There are no markings on tracheostomy tubes. Follow hospital procedures when advancing the catheter.
8. **(Fig. 3)** Depress and hold the vacuum control device(H).
9. **(Fig. 4)** Then gently withdraw catheter(D)until the black ring(F)is visible on the distal side of the patient-end adaptor.
10. Repeat steps 6-8 above as necessary.

Catheter Irrigation

1. **(Fig. 5)** Open cap on irrigation port (J) . A prefilled saline vial or a 15ml syringe filled with saline is prepared to be used.
2. **(Fig. 5)** Attached saline vial/syringe to the irrigation port.
3. Depress the cover of vacuum control device (H) for saline to enter the irrigation chamber (A) . Continue to irrigate until the catheter is clear of secretion.
4. Close the cap of irrigation port (J) .
5. **(Fig. 6)** Lock the cover of vacuum control device (H) when not in use to prevent accidental depression.
6. Turn off the vacuum after use. If the suction connection parts are disconnected, close cap (I) on the end of vacuum control device (G) .

Metered Dose Inhaler (MDI)

1. Remove cap of MDI port (K) , and attach canister. Avoid discharge of canister when connecting.
2. Hold canister in vertical position. Depress canister during inspiration cycle. Repeat as prescribed by physician or protocol.
3. Remove canister and close cap of MDI port (K) .

Disconnection

1. **(Fig. 7)** Disconnect the Sunset Deluxe closed suction system from the patient's airway by the disconnect wedge(M).
2. Set the disconnect wedge (M) between the airway connector and 15mm female connector (C) of closed suction system.
3. Lever up the wedge from the patient end adaptor to disconnect the closed suction system.
4. After use, the product must be disposed in conformance with the local disposal protocols and regulation of hygiene and medical waste.