INSTRUCTIONS FOR USE

FLEXIBLE CLOSED SUCTION CATHETERS

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biopharma

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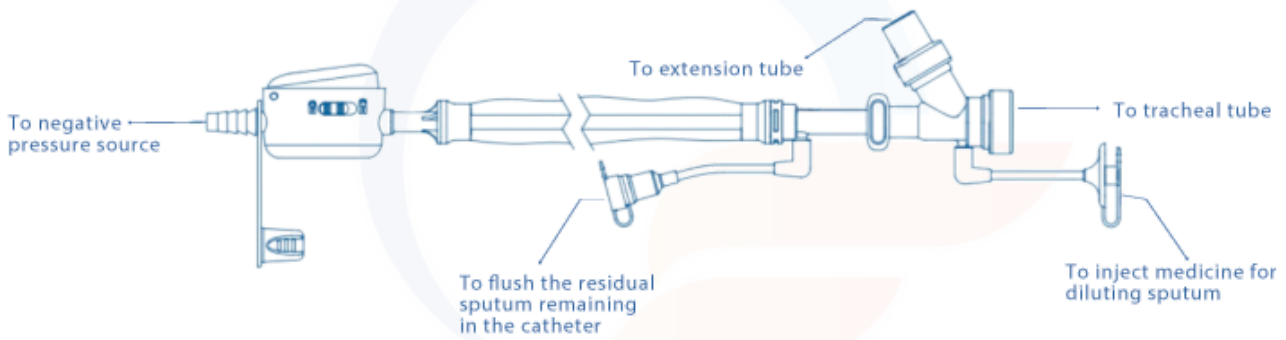
Flexible Closed Suction Catheters

Model 1512219

Size 14 FR

Parts Description:

The closed suction catheter is mainly constructed of machine end which includes protective cap (PVC) and suction control switch (ABS), catheter part which includes suction catheter (PVC) and protective sleeve (TPU), patient end which includes flushing system (PVC), MDI system (PVC),Y-patient end adaptor (PC), and Isolation valve (PC).



Product Description

The design of closed suction catheter complies with ISO 8836:2019. During clinical use, the negative pressure source (not included in this device) produce negative pressure and transfer the pressure into the device through suction control switch to suck the sputum out from the respiratory tract via endotracheal tube (invasive into body and not included in this device. The isolation valve shall be closed after suction process to close the suction catheter space.

The closed suction catheters will be connected with endotracheal tube and negative pressure source in clinical use, the device itself does not include endotracheal tube and negative pressure source and will not invasive into human body. It is put into market in ETO sterile condition and for single use.

Performance Index

- Ethylene oxide residue: The ethylene oxide residue shall be not more than 4mg/pc.\
- Sterility: The device shall be sterile after sterilization with ethylene oxide.
- Shaft performance: The shaft of the suction catheter shall not collapse at the maximum vacuum value of 40 kPa.

Intended Use

The closed suction catheters are intended to be used as a conduit to remove sputum from respiratory tract.

Contraindication

1. Patients that have hypersensitivity or vasovagal response to suctioning.
2. Patients with epiglottitis.
3. Nasotracheal suctioning on patients with thrombocytopenia, on systemic anticoagulant therapy, or have had recent surgery or trauma to the pharynx.
4. Airway tube sizes less than 5.0mm inner diameter.

⚠ Precaution:

1. Ensure that the correct size of closed suction catheter is used with the patients' endotracheal tube.
2. Destroy the device after use, disposal shall be in accordance with all applicable regulations.

⚠ Warning

1. Do not use after expiration date.
2. Do not use if the package is open or damaged.
3. For single patient use only. Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
4. Care should be taken during catheter insertion, fixation, and removal to avoid accidental or intentional cutting, suturing to or puncturing of the closed suction catheter as tearing of the catheter may result, causing device failure, patient injury, illness or death.
5. Only trained medical professionals could use the device.
6. Patients who are allergic to PVC material are forbidden to use.
7. Use with date sticker to identify the replacing date (if applicable).

Set up

Step 1: Ensure that the correct size of closed suction catheter is used with the endotracheal tube. Check if there is any damage to the package and open the device.

Step 2: Open the protective cap, attach the male end to the wall suction tubing, the patient connection port to endotracheal tube, the breathing machine end to ventilator tubing.

Step 3: Adjust the negative pressure to 150-200 mmHg.

Suction method

Step 4: Open the isolation valve (if applicable) and insert the catheter down the endotracheal tube to the desired depth.

Step 5: 0.9% saline can be added through the MDI (metered dose inhaler) system if required for patients with thick secretions. Step 6: Apply suction by depressing the press button and slowly withdraw the catheter and closed the isolation valve (if applicable).

Step 7: To clean the catheter, ensure the catheter is in the fully withdrawn position and add 0.9% saline to the flushing system whilst depressing the press button.

Step 8: Separate the device from wall suction tubing, close the male end with protective cap, and close the negative pressure source.

Step 9: Attach the correct day sticker to the suction control switch.

Note: MDI system is for drug delivery used with syringe.

Transportation and storage

1. The device shall be stored in a non-corrosive gas, relative humidity NMT 80% and clean environment.
2. Avoid hard pressure, direct sunlight, and rain-snow exposure.

Packaging marks

No.	Symbol	Meaning	No.	Symbol	Meaning
1		DATE OF MANUFACTURE	9		STERILIZED USING ETHYLENE OXIDE
2		DO NOT REUSE	10		CONSULT INSTRUCTIONS FOR USE
3		CAUTION	11		USE BY
4		MANUFACTURER	12		FRAGILE, HANDLE WITH CARE
5		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	13		DO NOT USE IF PACKAGE IS DAMAGED
6		THE PRODUCT HAS PASSED CE CERTIFICATION	14		KEEP DRY
7		BATCH CODE	15		KEEP AWAY FROM SUNLIGHT
8		CATALOGUE NUMBER	16		DO NOT RESTERILIZE

 The device is sterilized by ethylene oxide, and the shelf life is 3 years after sterilization.

Manufactured for Dr. Ferrer Biopharma
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