

Instructions for use



[Product Name]

Closed Suction Catheter

[Intended Purpose]

It is intended for use in suctioning of the respiratory tract for clinical patients.

[Type(s)/Size(s)/Component(s)]

See attachment 1

[Indication]

The product is used by medical units to absorb sputum from the respiratory tract of clinical patients.

[Contraindications]

No absolute contraindication.

[Patient target group]

Suitable for patients who need sputum aspiration.

[Intended Users]

Professional medical staff.

[Use Method]

- 1) Please read the instruction manual carefully before using the product.
- 2) Select the appropriate model and specifications of the product.
- 3) Open the packaging bag, check whether the machine end protective cap, medicine injection and cleaning valve cap are closed, and connect the patient end unit to the endotracheal tube and the ventilator pipeline respectively.
- 4) Take off the protective cap of the machine end unit and connect it with the suction connection tube connector.
- 5) Patient end operation: For non-sputum suction operation, if there is a double position switch, push it to the off state; if there is a rotary switch, turn it counterclockwise to the off state. During suction operation, if there is a double position switch, push the double position switch to the on state; if there is a rotary switch, turn it clockwise to the on state, and then slowly feed the suction catheter into the tracheal tube and pay attention to the scale on the observation tube to control the depth of delivery.
- 6) Machine end operation: During non-sputum suction operation, if there is a pressing type negative pressure control handle, it will not be operated; if there is a pushing wheel type negative pressure control handle, the pushing wheel must be pushed to the left side (patient end direction) to close; if there is an auto-lock press control handle, the auto-lock button must be

pulled up and rotated to lock state; during suction operation, if there is a pressing type negative pressure control handle, press the negative pressure control switch down; if there is a pushing wheel type negative pressure control handle, you need to open the pushing wheel to the right (machine end direction); if there is an auto-lock press control handle, the auto-lock button needs to be pulled up and rotated to a depressible state. It needs to be pressed down, and then the medical suction equipment is turned on to suck sputum.

- 7) At the end of the suction operation:
 - Close medical suction equipment, slowly pull out the suction catheter until the transparent sheath is straightened (At this point, you can see that the head of the suction catheter has been retracted into the front end interface.). If there is a double position switch, turn off the double position switch; if there is a rotary switch, turn it to the off state.
- 8) Cleaning: If there is a double position switch, the double position switch should be placed in the closed state. If there is a rotary switch that needs to be turned to the closed state, First turn on the medical suction equipment, then turn on the machine end switch, and finally turn on the cleaning valve cap and connect with the Syringe or infusion connecting tube for flushing. After flushing, turn off the cleaning valve cap and the medical suction equipment (at this time, the machine end is closed)

[Warnings and Precautions]

- 1) The product has been sterilized with ethylene oxide with validity for five years.
- 2) This product needs to be operated and used by professional medical staff.
- 3) Check whether the package is complete. If the package is damaged, do not use it.
- 4) Tear open the exterior package to check whether the device in the package is in sound and good condition. Do not use if damaged.
- 5) This product is for single use. It is recommended to replace the suction catheter every 72 hours. Please destroy it after use.
- 6) It is recommended that each sputum suction should not exceed 15 seconds (for those with thick sputum, the humidification fluid can be injected through the cleaning tube seat).
- 7) After the suction operation is completed, the head end of suction catheter is required to retract to the cleaning room (the black indication line is above the clamp) to avoid clogging the airway.
- 8) In the process of suctioning, pay attention to observing the patient's vital signs and faces, the color of the lip, if

there is an abnormality to report the doctor for treatment.

- 9) When the suction control operation is not performed, if there is a double position switch or rotary switch, pull the suction tube to the specified position and turn off the double position switch or rotary switch, otherwise the suction catheter may be squeezed or damage.
- 10) Please master the correct suction catheter flushing method: turn on the Medical suction equipment before flushing, and then inject the sterile normal saline, close the syringe or infusion connecting tube after flushing, and turn off the negative pressure suction machine after the sputum in the suction catheter is fully rinsed and avoid getting liquid into the airway. In all stances, the connector of flushing shall be compatible with a male small bore connector complying with ISO 80369-7
- 11) When used in conjunction with the tracheal tube, it should be noted that the suction catheter should be completely taken out of the tracheal tube before the tracheal tube is separated from the human body.
- 12) According to the relevant regulations of hospitals or local health and family planning authorities, the destruction procedures shall be handled harmlessly by qualified or authorized institutions.
- 13) Please inform the manufacturer and competent authority in case of any adverse events related to the device occur.

[Shelf-life]

Five years

[Sterilization Method]

Ethylene oxide

[Storage and Transport Conditions]

Avoid squeezing or colliding products during transportation to avoid damage to the equipment.

The packaged product should be stored away from fire, the relative humidity is 45% RH~75%RH, no corrosive gas, well ventilated and clean environment.

[Production Date]

See on the package.

[Symbol Explanation]

	Manufacturer		Do not re-use
	Batch code		Use-by date
	Date of manufacture, country of manufacture		Catalogue number
	Do not use if package is damaged and consult		Authorized representative

	instructions for use		
	Sterilized using ethylene oxide		Do not re-sterilize
	Consult instructions for use or consult electronic instructions for use		Unique device identifier
	Single sterile barrier system		Medical device
	Keep away from sunlight		Keep dry
	Caution		CE Marking
	Fragile, handle with care		Stacking layer limit
	Upwards		Not made with natural rubber latex

[Manufacturer]

Henan Tuoren Medical Device Co., Ltd.
 Address: Weiyuan Industrial Zone, Menggang, Changyuan, 453400 Henan Province, P.R. China
 Tel.: +86 373-8605444
 E-mail: info@bjtuoren.com
 e-IFU: <http://en.tuoren.com/ifu>

[EU Representative]

MedNet EC-REP CIII GmbH
 Address: Borkstrasse 10, 48163 Münster, Germany

[Issue date]

YYYY-MM-DD

[Latest revision]

A/4

[Attachment 1]

REF	Type	Size	Components		
SCCVA5	VA Type	5Fr	Endotracheal Tube Connector; Cleaning Elbow; Double position switch; Screw Cap; Four-way Connector; Connecting Tube; Cleaning Tube Seat; Suction Catheter; Clamp; Handle Connector; Autolock press control handle; Protective Cap; Transparent Sheath; Sealing Core; Four-way; Breathing Circuit Connector; Rotating Sleeve of Breathing Circuit Connector;		
SCCVA6		6Fr			
SCCVA7		7Fr			
SCCVA8		8Fr			
SCCVA10		10Fr			
SCCVA10S		10Fr			
SCCVA12		12Fr			
SCCVA14		14Fr			
SCCVA16		16Fr			
SCCEA5	EA Type	5Fr	120-degree Four-way Breathing Circuit Connector; Ø22 Sealing Ring; 120-degree Four-way; Cleaning Elbow; Connecting Tube; Cleaning Tube Seat; Suction Catheter; Autolock Press Control Handle; Protective Cap; Handle Connector; Transparent Sheath; Clamp; Sealing Piece Fixing Plug; Sealing Piece; Simple Four-way Connector; Ø18 Sealing Ring; 120-degree Four-way Breathing Circuit Connector;		
SCCEA6		6Fr			
SCCEA7		7Fr			
SCCEA8		8Fr			
SCCEA10		10Fr			
SCCEA12		12Fr			
SCCEA14		14Fr			
SCCEA16				16Fr	
SCCPA5	PA Type	5Fr	Pediatric Connector Base; Pediatric 3-way; Simple Four-way Connector; Cleaning Elbow; Connecting Tube; Cleaning Tube Seat; Sealing Piece; Sealing Piece Fixing Plug; Clamp; Suction Catheter; Transparent Sheath; Handle Connector; Autolock Press Control Handle; Protective Cap;		
SCCPA6		6Fr			
SCCPA7		7Fr			
SCCPA8		8Fr			
SCCPA5S		5Fr			
SCCPA6S		6Fr			
SCCPA7S		7Fr			
SCCPA8S		8Fr			
SCCRA5	RA Type	5Fr	Rotary Endotracheal Tube Connector; Ø15 seal ring; Rotary Switch; Sealing Piece; Sealing Piece Fixing Plug; Clamp; Suction Catheter; Transparent Sheath; Self-locking Press Control Handle; Protective Cap; Handle Connector; Cleaning Tube Seat; Connecting Tube; Cleaning Elbow; Rotary Four-way; Ø13 Seal Ring; Rotary Circuit Connector;		
SCCRA6		6Fr			
SCCRA7		7Fr			
SCCRA8		8Fr			
SCCRA10		10Fr			
SCCRA12		12Fr			
SCCRA14		14Fr			
SCCRA16				16Fr	
SCCRAT5		5Fr			
SCCRAT6		6Fr			
SCCRAT7		7Fr			
SCCRAT8		8Fr			
SCCRAT10		10Fr			
SCCRAT12		12Fr			
SCCRAT14		14Fr			
SCCRAT16				16Fr	
SCCDA5	DA Type	5Fr	120 Degree Endotracheal Tube Connector; Ø22mm Seal Ring; 120 Degree Breathing Circuit Connector; Ø18mm Seal Ring;		
SCCDA6		6Fr			
SCCDA7		7Fr			
SCCDA8		8Fr			

REF	Type	Size	Components		
SCCDA10		10Fr	Valve Automatic Switch; Switch Type Four-way; Cleaning Elbow; Connecting Tube; Cleaning Tube Seat; Sealing Piece; Sealing Piece Fixing Plug; Clamp; Suction Catheter; Transparent Sheath; Handle Connector; Self-locking Press Control Handle; Protective Cap;		
SCCDA12		12Fr			
SCCDA14		14Fr			
SCCDA16		16Fr			
SCCVP5	VP Type	5Fr	Endotracheal Tube Connector; Cleaning Elbow; Double Position Switch; Screw Cap; Four-way Connector; Connecting Tube; Cleaning Tube Seat; Suction Catheter; Clamp; Handle Connector; Protective Cap; Transparent Sheath; Sealing Core; Four-way; Breathing Circuit Connector; Rotating Sleeve of Breathing Circuit Connector;		
SCCVP6		6Fr			
SCCVP7		7Fr			
SCCVP8		8Fr			
SCCVP10		10Fr			
SCCVP12		12Fr			
SCCVP14		14Fr			
SCCVP16				16Fr	
SCCEP5	EP Type	5Fr	120 Degree Four-way Endotracheal Tube Connector; Ø22 Sealing Ring; 120 Degree Four-way; Cleaning Elbow; Connecting Tube; Cleaning Tube Seat; Suction Catheter; Pressing Type Negative Pressure Control Handle; Protective Cap; Handle Connector; Transparent Sheath; Clamp; Sealing Piece Fixing Plug; Sealing Piece; Simple Four-way Connector; Ø18 Sealing Ring; 120-degree Four-way Breathing Circuit Connector;		
SCCEP6		6Fr			
SCCEP7		7Fr			
SCCEP8		8Fr			
SCCEP10		10Fr			
SCCEP12		12Fr			
SCCEP14		14Fr			
SCCEP16				16Fr	
SCCPP5	PP Type	5Fr	Pediatric Connector Base; Pediatric 3-Way; Simple Four-Way Connector; Cleaning Elbow ; Connecting Tube; Cleaning Tube Seat; Sealing Piece; Sealing Piece Fixing Plug; Clamp; Suction Catheter; Transparent Sheath; Handle Connector; Pressing Type Negative Pressure Control Handle; Protective Cap;		
SCCPP6		6Fr			
SCCPP7		7Fr			
SCCPP8				8Fr	
SCCRP5		RP Type		5Fr	Rotary Endotracheal Tube Connector; Ø15 Seal Ring; Rotary Switch; Sealing Piece; Sealing Piece Fixing Plug; Clamp; Suction Catheter; Transparent Sheath; Handle Connector; Pressing Type Negative Pressure Control Handle; Protective Cap; Cleaning Tube Seat; Connecting Tube; Cleaning Elbow; Rotary Four-way; Ø13 Seal Ring; Rotary Circuit Connector;
SCCRP6				6Fr	
SCCRP7				7Fr	
SCCRP8	8Fr				
SCCRP10	10Fr				
SCCRP12	12Fr				
SCCRP14	14Fr				
SCCRP16		16Fr			
SCCDP5	DP Type	5Fr	120-degree Four-way Endotracheal Tube Connector; Ø 22mm Seal Ring; 120 Degree Breathing Circuit Connector; Ø 18mm Seal Ring; Valve Automatic Switch; Switch Type Four-way; Cleaning Elbow; Connecting Tube; Cleaning Tube		
SCCDP6		6Fr			
SCCDP7		7Fr			
SCCDP8		8Fr			
SCCDP10		10Fr			
SCCDP12		12Fr			
SCCDP14	14Fr				

REF	Type	Size	Components
SCCDP16		16Fr	Seat; Sealing Piece; Sealing Piece Fixing Plug; Clamp; Suction Catheter; Transparent Sheath; Handle Connector; Pressing Type Negative Pressure Control Handle; Protective Cap;
SCCVW5	VW Type	5Fr	Endotracheal Tube Connector; Cleaning Elbow; Double Position Switch; Screw Cap; Four-way Connector; Connecting Tube; Cleaning Tube Seat; Suction Catheter; Clamp; Pushing Wheel Connecting Piece; Pushing Wheel Type Negative Pressure Control Handle; Machine End Connector; Machine End Connector Protective Cap; Transparent Sheath; Sealing Core; Four-way; Breathing Circuit Connector; Rotating Sleeve of Breathing Circuit Connector;
SCCVW6		6Fr	
SCCVW7		7Fr	
SCCVW8		8Fr	
SCCVW10		10Fr	
SCCVW12		12Fr	
SCCVW14		14Fr	
SCCVW16			
SCCEW5	EW Type	5Fr	120-degree Four-way Endotracheal Tube Connector; \varnothing 22 Sealing Ring; 120 Degree Four-way; Cleaning Elbow; Connecting Tube; Cleaning Tube Seat; Suction Catheter; Clamp; Pushing Wheel Connecting Piece; Pushing Wheel Type Negative Pressure Control Handle; Machine End Connector; Machine End Connector Protective Cap; Transparent Sheath; Sealing Piece Fixing Plug; Sealing Piece; Simple Four-way Connector; \varnothing 18 Sealing Ring; 120-degree Four-way Breathing Circuit Connector;
SCCEW6		6Fr	
SCCEW7		7Fr	
SCCEW8		8Fr	
SCCEW10		10Fr	
SCCEW12		12Fr	
SCCEW14		14Fr	
SCCEW16			
SCCPW5	PW Type	5Fr	Pediatric Connector Base; Pediatric 3-way; Simple Four-way Connector; Cleaning Elbow; Connecting Tube; Cleaning Tube Seat; Sealing Piece; Sealing Piece Fixing Plug; Clamp; Suction Catheter; Transparent Sheath; Pushing Wheel Connecting Piece; Pushing Wheel Type Negative Pressure Control Handle; Machine End Connector; Machine End Connector Protective Cap;
SCCPW6		6Fr	
SCCPW7		7Fr	
SCCPW8		8Fr	
SCCRW5	RW Type	5Fr	Rotary Endotracheal Tube Connector; \varnothing 15 Seal Ring; Rotary Switch; Sealing Piece; Sealing Piece Fixing Plug; Clamp; Suction Catheter; Transparent Sheath; Pushing Wheel Connecting Piece; Pushing Wheel Type Negative Pressure Control Handle; Machine End Connector; Machine End Connector Protective Cap; Cleaning Tube Seat; Connecting Tube; Cleaning Elbow; Rotary Four-way; \varnothing 13 Seal Ring; Rotary Circuit Connector;
SCCRW6		6Fr	
SCCRW7		7Fr	
SCCRW8		8Fr	
SCCRW10		10Fr	
SCCRW12		12Fr	
SCCRW14		14Fr	
SCCRW16			
SCCDW5	DW Type	5Fr	120-degree Endotracheal Tube Connector; \varnothing 22mm Seal Ring; 120-degree Breathing Circuit Connector; \varnothing 18mm Seal Ring;
SCCDW6		6Fr	
SCCDW7		7Fr	
SCCDW8		8Fr	

REF	Type	Size	Components
SCCDW10		10Fr	Valve Automatic Switch; Switch Type Four-way; Cleaning Elbow; Connecting Tube; Cleaning Tube Seat; Sealing Piece; Sealing Piece Fixing Plug; Clamp; Suction Catheter; Transparent Sheath; Pushing Wheel Connecting Piece; Pushing Wheel Type Negative Pressure Control Handle; Machine End Connector; Machine End Connector Protective Cap;
SCCDW12		12Fr	
SCCDW14		14Fr	
SCCDW16		16Fr	
Note: Product type: SCC (Closed Suction Catheter) Size: 5Fr, 6Fr, 7Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr Machine end type: M (A: Auto-lock controller, P: Pressing controller, W: Pushing wheel controller) Patient end type: P (V: 90° patient end, E: 120° patient end, P: Pediatric connector, R: Rotary switch patient end, D: Valve type) T: Tracheostomy Tube Connector S: Short length			