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Doc Title	<input type="text" value="Clie Closed Suction Catheter PDS"/>	Requestor	<input type="text"/>
Actions/ Changes	<input type="text" value="New PDS"/>		

PLEASE CHECK THE DOCUMENT CAREFULLY INCLUDING ALL
DESCRIPTIONS, MATERIALS, SPECIFICATIONS AND GRAMMAR.

APPROVAL 1

Amendments Required	<input type="text"/>
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Approved *Emma Longman*

APPROVAL 2

Amendments
Required

Approved

APPROVAL 3

Amendments
Required

Approved

APPROVAL 4

Amendments
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APPROVAL 5

Amendments
Required

Approved

CLIC™

Closed Suction Catheter

Product Data Sheet



DESCRIPTION / FUNCTION

The Clic™ Closed Suction Catheter is a single use device used to effectively clear patients' airways of accumulated mucosal secretions and improve respiratory function.

Closed suctioning is considered best practice to maintain ventilation and pressure levels, whilst minimising the risk of cross-contamination and infection to patients and healthcare professionals.

Advantages of Closed Suction Catheter use compared to conventional open suction techniques:

- Maintains a continuous closed ventilation system
- Protects ventilation and pressure levels, preventing hypoxemia and atelectasis
- Reduced risk of cross contamination and Ventilator Associated Pneumonia (VAP)
- Time saving and cost reduction, improved utilisation of resources
- Standardisation of clinical procedures, consistency of patient care

Maintenance of ventilation along with reduced risk of VAP are the two greatest benefits of Closed Suction Catheter use.

The Clic™ Closed Suction Catheter features an easy to use Thumb Valve with a built-in Bacterial/Viral Filter as an added safety feature. Air passing through the closed suction catheter is vented through the filter ensuring the patient, caregiver and environment are also protected, resulting in:

- Reduced environmental contamination risk on the outer surface of the stored catheter.
- Reduced exposure of airborne contaminants to the caregiver during catheter insertion.
- Enhanced cleanliness supporting the overall extended use of the catheter system.
- A low profile design which does not impede clinical practice.

WARNINGS / PRECAUTIONS

- Single use only.
- DO NOT re-sterilise.
- DO NOT reuse this device. Reuse may result in hazards such as, but not limited to; cross contamination, damage to device and/or suboptimal performance.
- The Closed Suction System is designed for use up to a maximum period of 7 days, or less if dictated by local policies, guidelines, or individual patient requirements.
- Change immediately if suction catheter becomes heavily soiled or function is affected.
- DO NOT use the Clic™ Closed Suction Catheter for Neonatal and Paediatric patients on adults.

- DO NOT use the Clic™ Closed Suction Catheter for Adults on paediatric or neonatal patients.
 - DO NOT use Tracheostomy length Clic™ Closed Suction Catheter for patients ventilated through an endotracheal tube artificial airway, as suctioning will be ineffective.
 - DO NOT use Adult Endotracheal length (540mm, 21.3 inches) or Paediatric Endotracheal length (405mm, 16 inches) Clic™ Closed Suction Catheter for patients ventilated through a tracheostomy tube, as mucosal damage and airway trauma may result.
 - ALWAYS use Tracheostomy length (305mm, 12 inches) Clic™ Closed Suction Catheter for patients ventilated through a tracheostomy tube.
 - If a Heat and Moisture Exchanger (HME) is used excess fluid may increase gas flow resistance. When introducing fluid into T-Piece, ensure that fluid does not enter the HME.
 - ALWAYS exercise caution to avoid inserting the suction catheter too far into the tracheobronchial tree.
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- ALWAYS fully withdraw the suction catheter prior to trimming the endotracheal tube to avoid also cutting the suction catheter.
 - ALWAYS remove the T-Piece cap before starting continuous flow therapy. Failure to do so may result in serious injury or death.
 - Use vacuum levels less than 150mm Hg for Adults.
 - Use vacuum levels less than 100mm Hg for neonates.
 - Select the appropriate suction catheter size according to hospital protocol and local guidelines.
 - The recommended guideline is multiply the endotracheal tube inner diameter by 2, use the next smallest suction catheter size if between sizes.
 - Atelectasis may result from attempting to suction through a large suction catheter in a small airway.
 - ALWAYS withdraw the suction catheter until the proximal mark (black stripe) is visible within the sleeve. Withdrawal of the suction catheter beyond the wiper seal may inflate the protective sleeve. Any suction catheter remaining in the airway will cause increased airway resistance.
 - DO NOT leave the suction catheter within the airway.
 - ALWAYS follow suction equipment manufacturer's Instructions for Use, physician's prescription, hospital protocol and local guidelines to set the suction level.
 - ALWAYS use appropriate suctioning technique according to hospital protocol and local guidelines.
 - ALWAYS use caution and good clinical judgment no matter what ventilator mode setting is used. Follow the ventilator manufacturer's Instructions for Use to adjust the ventilator settings if there are signs of suction intolerance such as oxygen desaturation, negative ventilator system pressures, patient stress or excessive discomfort.
 - ALWAYS place the suction thumb valve in the locked position when not in use to prevent inadvertent activation.
 - ALWAYS attach the appropriate day label to the irrigation port tubing at time of fitting to indicate the day when the Clic™ Closed Suction Catheter is to be exchanged.

SPECIFICATION / KEY FEATURES

- For use with Adult, Paediatric and Neonatal patients
- Built-in Bacterial Viral Filter
- Two unique double swivel adapters for endotracheal & tracheostomy tubes
- Tracheostomy T-Piece adapter
- Neonatal & Paediatric Y- piece connectors
- CO₂ Monitoring Port
- Metred Dose Inhaler Medication Port
- PRN use, up to 7 days change-out

PRODUCT RANGE & PART NUMBERS

Product Code	Product Description
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050-63-110	Adult ET Closed Suction Catheter Size 10Fr 540mm (21.3") with T-Piece
050-63-112	Adult ET Closed Suction Catheter Size 12Fr 540mm (21.3") with T-Piece
050-63-114	Adult ET Closed Suction Catheter Size 14Fr 540mm (21.3") with T-Piece
050-63-116	Adult ET Closed Suction Catheter Size 16Fr 540mm (21.3") with T-Piece
050-63-210	Adult Tracheostomy Closed Suction Catheter Size 10Fr 305mm (12") with T-Piece
050-63-212	Adult Tracheostomy Closed Suction Catheter Size 12Fr 305mm (12") with T-Piece
050-63-214	Adult Tracheostomy Closed Suction Catheter Size 14Fr 305mm (12") with T-Piece
050-63-216	Adult Tracheostomy Closed Suction Catheter Size 16Fr 305mm (12") with T-Piece
050-64-110	Adult ET Closed Suction Catheter Size 10Fr 540mm (21.3") with Double Swivel Elbow
050-64-112	Adult ET Closed Suction Catheter Size 12Fr 540mm (21.3") with Double Swivel Elbow
050-64-114	Adult ET Closed Suction Catheter Size 14Fr 540mm (21.3") with Double Swivel Elbow
050-64-116	Adult ET Closed Suction Catheter Size 16Fr 540mm (21.3") with Double Swivel Elbow
050-64-210	Adult Tracheostomy Closed Suction Catheter Size 10Fr 305mm (12") with Double Swivel Elbow
050-64-212	Adult Tracheostomy Closed Suction Catheter Size 12Fr 305mm (12") with Double Swivel Elbow
050-64-214	Adult Tracheostomy Closed Suction Catheter Size 14Fr 305mm (12") with Double Swivel Elbow
050-64-216	Adult Tracheostomy Closed Suction Catheter Size 16Fr 305mm (12") with Double Swivel Elbow
050-62-105	Neonatal Closed Suction Catheter Size 5Fr 305mm (12") with Y-Sets 2.0/2.5mm
050-62-106	Infant Closed Suction Catheter Size 6Fr 305mm (12") with Y-Sets 2.5/3.0/3.5mm
050-62-107	Infant Closed Suction Catheter Size 7Fr 305mm (12") with Y-Sets 3.0/3.5/4.0mm
050-62-108	Infant Closed Suction Catheter Size 8Fr 305mm (12") with Y-Sets 3.5/4.0/4.5mm
050-62-110	Paediatric Closed Suction Catheter Size 10Fr 405mm (16") with Y-Sets 4.5/5.0/5.5mm
050-65-410	Adult ET Closed Suction Catheter Size 10Fr 540mm with Double Swivel Elbow and Medication Port
050-65-412	Adult ET Closed Suction Catheter Size 12Fr 540mm with Double Swivel Elbow and Medication Port
050-65-414	Adult ET Closed Suction Catheter Size 14Fr 540mm with Double Swivel Elbow and Medication Port
050-65-416	Adult ET Closed Suction Catheter Size 16Fr 540mm with Double Swivel Elbow and Medication Port
050-65-310	Adult ET Closed Suction Catheter Size 10Fr 540mm with Double Swivel Elbow and EtCO ₂ Port
050-65-312	Adult ET Closed Suction Catheter Size 12Fr 540mm with Double Swivel Elbow and EtCO ₂ Port
050-65-314	Adult ET Closed Suction Catheter Size 14Fr 540mm with Double Swivel Elbow and EtCO ₂ Port
050-65-316	Adult ET Closed Suction Catheter Size 16Fr 540mm with Double Swivel Elbow and EtCO ₂ Port
050-63-110U	Adult ET Closed Suction Catheter Size 10Fr 540mm (21.3") with T-Piece
050-63-112U	Adult ET Closed Suction Catheter Size 12Fr 540mm (21.3") with T-Piece
050-63-114U	Adult ET Closed Suction Catheter Size 14Fr 540mm (21.3") with T-Piece
050-63-116U	Adult ET Closed Suction Catheter Size 16Fr 540mm (21.3") with T-Piece
050-63-210U	Adult Tracheostomy Closed Suction Catheter Size 10Fr 305mm (12") with T-Piece
050-63-212U	Adult Tracheostomy Closed Suction Catheter Size 12Fr 305mm (12") with T-Piece
050-63-214U	Adult Tracheostomy Closed Suction Catheter Size 14Fr 305mm (12") with T-Piece
050-63-216U	Adult Tracheostomy Closed Suction Catheter Size 16Fr 305mm (12") with T-Piece

050-64-110U	Adult ET Closed Suction Catheter Size 10Fr 540mm (21.3") with Double Swivel Elbow
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050-64-216U	Adult Tracheostomy Closed Suction Catheter Size 16Fr 305mm (12") with Double Swivel Elbow
050-62-105U	Neonatal Closed Suction Catheter Size 5Fr 305mm (12") with Y-Sets 2.0/2.5mm
050-62-106U	Infant Closed Suction Catheter Size 6Fr 305mm (12") with Y-Sets 2.5/3.0/3.5mm
050-62-107U	Infant Closed Suction Catheter Size 7Fr 305mm (12") with Y-Sets 3.0/3.5/4.0mm
050-62-108U	Infant Closed Suction Catheter Size 8Fr 305mm (12") with Y-Sets 3.5/4.0/4.5mm
050-62-110U	Paediatric Closed Suction Catheter Size 10Fr 405mm (16") with Y-Sets 4.5/5.0/5.5mm
050-65-410U	Adult ET Closed Suction Catheter Size 10Fr 540mm (21.3") with Double Swivel Elbow and Medication Port
050-65-412U	Adult ET Closed Suction Catheter Size 12Fr 540mm (21.3") with Double Swivel Elbow and Medication Port
050-65-414U	Adult ET Closed Suction Catheter Size 14Fr 540mm (21.3") with Double Swivel Elbow and Medication Port
050-65-416U	Adult ET Closed Suction Catheter Size 16Fr 540mm (21.3") with Double Swivel Elbow and Medication Port

MATERIALS

Component	Material
Endotracheal Tube Connector	Polypropylene, Silicone
Tracheostomy Tube Connector	Polypropylene, Silicone
Endotracheal Tube Ventilator Circuit Connector	Polypropylene, Silicone,
Tracheostomy Tube Ventilator Circuit Connector	ABS (Acrylonitrile Butadiene Styrene), TPE
CO ₂ Monitoring Port	Polypropylene, ABS, PVC (polyvinyl chloride)
Medication Port	PVC
Irrigation Port	PVC, ABS
Suction Catheter Sleeve	TPU
Suction Catheter	PVC
Suction Catheter Sleeve Adapter	Polypropylene
Bacterial/Viral Filter	ABS, PTFE
Thumb Valve	ABS, Silicone
Aspirator Connector	ABS
Aspirator Connector Cap	EVA
Neonatal Y Connector	ABS
Separating Wedge	ABS
Flexilock Tubing	PE/EVA

LATEX CONTENT

Flexicare's Closed Suction Catheter does not contain natural rubber latex.

DEHP CONTENT

Flexicare's Closed Suction Catheter does not contain phthalate DEHP.

SINGLE USE

Flexicare's Closed Suction Catheter is a single patient use device.

STERILITY

Flexicare's Closed Suction Catheter is supplied sterile.

STORAGE

Store in a cool, dry place out of direct sunlight.

DISPOSAL CONSIDERATIONS

Closed Suction Catheters should be disposed in accordance with local policies, local guidelines, and regulations.

PACKAGING MATERIALS

Pouch – Tyvek 2FS / Nylon

Box - Cardboard






Closed Suction Catheter PDS

Final Audit Report

2022-09-21

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