INSTRUCTION FOR USE

- ***Product Name*** : SUCTION CATHETER
- ***Brand Name*** : Ultramed suction catheter.
- ***Manufacturer's Name*** : Ultra for Medical Products (ULTRAMED) Co. (U.M.I.C) S.A.E
- ***Manufacturer's Address*** : Part No. (304:310) & part no. (312) – Industrial Area, Arab El Awamer – Abnoub - Assiut – Egypt.

- ***Description of the Device:***

- ❖ Suction catheters are medical devices used to remove fluids, secretions and debris from patient's airway or respiratory tract.
- ❖ Suction catheter is made of soft tube with smooth, well rounded and edge free open tip.
- ❖ This distal open tip is preceded by two smooth surface, edge free lateral eyes for enabling efficient drainage.
- ❖ The proximal end features a funnel connector to be attached to a controlled suction apparatus, enabling the effective suction and allowing healthcare professionals to maintain clear airways and prevent respiratory complications.
- ❖ Suction catheters are commonly used in hospitals, clinics, and other healthcare settings, especially for patients who have difficulty clearing their airways due to conditions like pneumonia, bronchitis or during surgical procedures under anesthesia.
- ❖ There are two different types of connectors for suction catheters:
- ❖ The Thumb-Control connector has the feature of an attached cap that can fit the Pressure release outlet and increase the suction pressure to the maximum. This provides the user a means of getting the catheter to suck at maximum negative pressure without having to apply his or her thumb continuously over the control outlet. The cap can be easily detached with a slight tug if the user does not wish to use it.
- ❖ The Plain Connector helps to attach the tube with the vacuum source or machine
- ❖ The length of suction catheters is 50 cm.
- ❖ Available sizes for suction catheter with plain connector are from 6 to 24 FG and for suction catheter with thumb control connector are from 5 to 24 FG
- ❖ Each suctioning event should be as brief as possible and no longer than 15 seconds.
- ❖ The product is sterilized using EO (Ethylene Oxide)

- This product is for single use.

- ULTRAMED suction catheter (with or without thumb control)

- A smooth rounded tip is less traumatic to the patient.
- Two lateral eyes
- Color-coded connector for easy identification of sizes.
- A thumb controller, allowing control of suctioning.
- Soft and kink-resistant tube (Medical grade PVC) non-allergenic (Phthalate free / DEHP free)
- Suction Catheter Length:50 cm
- Single peel pack, Sterile, Ready for use

- The quantity in the multi-unit PE bag container varies according to the size.

Size	Quantity in the multiunit PE bag container
From 6 FG to 10 FG	35 Pcs
From 12 FG to 24 FG	25 Pcs
Suction Catheter with thumb control From 5 FG to 24 FG	25 Pcs

- Box contains 5 PE bag for Suction Catheter with plain connector and contains 4 PE bag for Suction Catheter with thumb control.
- The quantity in the outer carton varies according to the size

Size	Quantity in the Outer Carton
Suction Catheter with plain connector From 6 FG to 10 FG	2100 Pcs
Suction Catheter with plain connector From 12 FG to 16 FG	1500 Pcs
Suction Catheter with plain connector From 18 FG to 24 FG	750 Pcs
Suction Catheter with thumb control From 5 FG to 16 FG	1200 Pcs
Suction Catheter with thumb control From 18 FG to 24 FG	600 Pcs

- Material Used:

- Poly Vinyl Chloride

- Intended purpose:

- The product is used to provide access to respiratory tract to remove secretion from Oro-pharyngeal & Tracheo-bronchial regions.in critically ill patients

with weak ability to spontaneously clear secretions and debris with maximum comfort to the patient. The purpose of suctioning is to keep the airways clear of secretions and prevent plugging of the airways.

- Additionally, suctioning is performed to maintain the patency of artificial airways such as an endotracheal tube or a tracheostomy tube.

- Variants:

Code	**Item**
2001-6	Suction Catheter Sizes 6 FG (Plain)
2001-8	Suction Catheter Sizes 8 FG (Plain)
2001-10	Suction Catheter Sizes 10 FG (Plain)
2001-12	Suction Catheter Sizes 12 FG (Plain)
2001-14	Suction Catheter Sizes 14 FG (Plain)
2001-16	Suction Catheter Sizes 16 FG (Plain)
2001-18	Suction Catheter Sizes 18 FG (Plain)
2001-20	Suction Catheter Sizes 20 FG (Plain)
2001-22	Suction Catheter Sizes 22 FG (Plain)
2001-24	Suction Catheter Sizes 24 FG (Plain)
2002-5	Suction Catheter Sizes 5 FG (with Thumb Control)
2002-6	Suction Catheter Sizes 6 FG (with Thumb Control)
2002-8	Suction Catheter Sizes 8 FG (with Thumb Control)
2002-10	Suction Catheter Sizes 10 FG (with Thumb Control)
2002-12	Suction Catheter Sizes 12 FG (with Thumb Control)
2002-14	Suction Catheter Sizes 14 FG (with Thumb Control)
2002-16	Suction Catheter Sizes 16 FG (with Thumb Control)
2002-18	Suction Catheter Sizes 18 FG (with Thumb Control)
2002-20	Suction Catheter Sizes 20 FG (with Thumb Control)
2002-22	Suction Catheter Sizes 22 FG (with Thumb Control)
2002-24	Suction Catheter Sizes 24 FG (with Thumb Control)

- Available sizes:

FG	Nominal outside diameter	Minimum Inner Diameter	Colour
5	1.66mm	0.80mm	Grey
6	2.00mm	1.00mm	Light green
8	2.66mm	1.50mm	Light blue
10	3.33mm	2.00mm	Black
12	4.00mm	2.45mm	White
14	4.66mm	2.95mm	Green

16	5.33mm	3.40mm	Orange
18	6.00mm	3.90mm	Red
20	6.66mm	4.30mm	Yellow
22	7.34mm	5.10mm	Violet
24	8.00mm	5.70mm	Blue

- Clinical Indications:

- Suction catheter is used in managing excessive respiratory secretions associated with Chronic respiratory conditions like COPD, pneumonia, and secondary infections because it helps clear the airway, reduces coughing, maintains a clear airway, and prevents complications like hypoxia.
- Emergency suctioning is crucial in respiratory emergencies, protecting airways from inflammation and swelling, and aiding those with acute respiratory infections who cannot clear their own airway.
- Pediatric airway management is crucial for respiratory emergencies, especially in premature infants and children with respiratory infections, choking episodes, or neurological conditions.
- Patients with artificial airways, including endotracheal tubes (ETT), tracheostomy tubes, or those on mechanical ventilation, require regular suctioning to clear airway secretions and maintain adequate ventilation.
- Suction catheters in hospital settings can help maintain a patent airway during surgery, reducing risks associated with general anesthesia, particularly in patients with respiratory disorders or high aspiration risk.
- Post-operative Care: After surgeries, especially those involving the respiratory tract or the upper airway, suctioning may be needed to clear excess mucus, blood, or other secretions.
- Neurological Conditions: Patients with neurological disorders, such as stroke or spinal cord injuries, may not have the ability to cough or clear secretions effectively, requiring suctioning.

- Contra indications:

- Do not Use in patient with a known allergic reaction to any of the product components
- Do not use in patients with Severe facial or airway trauma, severe bleeding disorders, severe bronchospasm, an irritable airway, or those who have undergone recent nasal, oral, or esophageal surgery, unexplained hemoptysis, Severe gag reflex, Occluded nasal passage, nasal bleeding.

- ***Device Limitation:***
  - ❖ Do not use suction catheters to deliver fluids or medications into the airway; they are not designed or approved for this purpose.
  - ❖ Do not use suction catheters to aspirate from surgical cavities, drains, or other body compartments.
  - ❖ Do not connect suction catheters to an oxygen source; this is dangerous and considered off-label use.
  - ❖ Do not use suction catheters for prolonged suctioning; they are designed for intermittent use, generally ≤15 seconds, to reduce the risk of hypoxia.
  - ❖ Do not use suction catheters without an appropriate connection to a regulated suction source; connecting to non-standard suction systems can result in inconsistent or unsafe suction pressures.
- ***Patient Target Group:***
  - ❖ No specific requirements or restrictions on use for patient population or user group defined by the manufacturer.
  - ❖ Adult, Pediatrics and Neonate
  - ❖ It is used for male and female patients (all Ages).
  - ❖ Suctioning is performed when the patient is unable to effectively remove secretions from the respiratory tract.
  - ❖ The current American Association for Respiratory Care clinical practice guidelines recommend choosing suction catheter size based on the external diameter of the suction catheter and the internal diameter of the endo-tracheal tube: a ratio of less than 50% is recommended, to prevent suctioning-related complications.
  - ❖ Patients with excessive production of secretions or ineffective clearance, which leads to the accumulation of secretions in the upper and lower respiratory tract.
- ***Intended User:***
  - ❖ To be used by an expert qualified medical professional, Skilled or Trained Personnel (In-Charge)
- ***Application site in the body:***
  - ❖ It is normally introduced through the nose or mouth, and may also be introduced through an endotracheal tube, tracheostomy or a Guedel airway, coming into direct contact with the mucosal membranes of the respiratory tract (e.g., pharynx, trachea).
- ***Replacement Frequency:***
  - ❖ Change the device immediately upon suspected contamination.

- ***Clinical benefits:***
  - ❖ Suction catheters are medical devices used to remove fluids, secretions, and debris from patient's airway or respiratory tract.
- ***Use Environment:***
  - ❖ Hospital, Emergency Room, Critical care room
- ***Life time of device:***

❖ Each suctioning event should be as brief as possible and no longer than 15 seconds.
❖ The suction catheter may be used for multiple suction passes during a single clinical procedure, but must be discarded immediately after use to prevent cross-contamination or infection risk.
❖ **Do not reuse** the suction catheter. This device is intended for **single-use only**.
❖ **Do not re-sterilize** or reprocess the catheter after use.
❖ **Do not use** the suction catheter if the packaging is damaged or has been previously opened.
❖ **Do not store** the catheter for future use once removed from sterile packaging. Dispose of properly after use.

- ***Sterility status and Method of sterilization:***
  - ❖ The suction catheter is supplied in sterile state and sterilized using ethylene oxide.
- ***Information on medical device intended to be used with other devices:***

❖ The suction catheter is designed to be connected with a suction source by providing a universal connector compatible to fit with the suction source to create negative pressure which allows healthcare professionals to effectively remove fluids, secretions and debris from patient's airway.

❖ It can be used with endotracheal tube, tracheostomy or Guedel Airway.

- ***Performance Characteristics:***

❖ A smooth rounded tip is less traumatic to the patient.
❖ Two lateral eyes
❖ Color-coded connector for easy identification of sizes.
❖ Thumb controller, allowing control of suctioning.
❖ Soft and kink-resistant tube (Medical grade PVC) (Phthalate free / DEHP free).
❖ Suction Catheter Length:50 cm
❖ Single peel pack, Sterile, Ready for use

Instruction for Use:

- ❖ ***preparation***

1. A regulated / controlled vacuum source, oxygen source, sterile gloves, stethoscope, water base sterile lubricant, collecting bottle and Suction Catheter, normal saline, and, or sterile water for rinsing should be prepared and ready prior to suction.

2. Personal protective equipment should always be used and includes a gown, mask, and preferably goggles. Use of sterile gloves is recommended.
3. Select the appropriate size of suction catheter, ensuring it is less than 50% of the internal diameter of the ETT or tracheostomy **if used with them**.
4. The recommended size of suction catheter should be one third of the size of the nostrils.
5. Check the packing carefully, if packing is found damaged, torn or pierced, discard the piece.
6. Wash-up and scrub hands and preferably use sterile protective gloves.
7. Position the patient appropriately to ensure effective suctioning and prevent complications like aspiration or injury.

❖ ***<u>During the procedure</u>***

8. Peel open the pouch and take out the device aseptically.
9. Check integrity of the device.
10. Connect the universal funnel connector of suction catheter to the regulated / controlled vacuum source.
11. Test for adequate suction by Turning on the suction machine and check for negative pressure. To do this, kink the connecting tubing with the machine running and note the reading on the gauge.
12. Adjust the suctioning pressure as appropriate for adults, children, and infants.
13. Lubrication of the ends of the catheter with sterile water-based lubricant. Suction catheters may require lubrication for easier insertion, particularly for nasopharyngeal suctioning.
14. Extra care should be taken while suctioning the airway in children because they have narrow airway, difficult access ability, and relative deleterious effects from small changes in pressure, oxygen saturations, and lung volumes.
15. Without applying suction pressure, gently insert the Suction Catheter distal end-smooth, soft & coned open tip suitably into the oro-pharyngeal cavity / patient's airway as per case. Either, directly or through already inserted Guedel Airways/ Tracheal Tube/ Tracheotomy Tube / Closed Suction System, etc.
16. If patient starts to cough or gag wait until the patient recovers before continuing.
17. Do not force catheter in when experiencing resistance, reinsert catheter if needed.
18. Never apply suction while inserting the catheter, as this can damage the airway
19. The catheter should be inserted until resistance is met or the end of the airway is reached (not deeper than necessary).
20. Withdraw catheter slightly (1-2mm) prior to applying suction.
21. Once the catheter is in position, apply suctioning.
22. In case of thumb connector, apply suctioning by placing thumb on the thumb controller connector.

23. Continue suctioning during the withdrawal of the catheter in a rotating motion.
24. Each suctioning event should be as brief as possible and no longer than 15 seconds.
25. Avoid prolonged suctioning to prevent hypoxia
26. If suctioning is required again, repeat the process after a brief pause to allow the airway to recover and prevent excessive irritation.
27. Care should be taken to maintain and normalize vital signs in between suction episodes with special attention to the heart rate and oxygen saturation levels.
28. If the patient is being artificially ventilated and needs to be suctioned again, you should continue to ventilate the patient for two minutes and then suction again, if needed, for up to 15 seconds and continue in this manner.
29. If necessary, rinse the catheter with sterile water or saline to prevent obstructions of the catheter.
30. Observe vital signs: Check the patient's pulse, respiratory rate, and oxygen saturation (pulse oximeter) before, during, and after suctioning.
31. Auscultate lung sounds: Listen for any changes in lung sounds, such as wheezing or crackles, which could indicate airway improvement or further blockage.
32. Observe secretion aspirated (e.g. Amount, color, tenacity, any blood in secretion, etc.)

- ***After the procedure***

33. After finishing, Discard the catheter.
34. Assess the patient for any signs of complications such as bleeding, trauma, or increased respiratory distress following the procedure
35. Adopt adequate precautions for the elimination and disposal of the device and comply with the provisions of the laws in force on biologically hazardous waste.

- ***Warnings:***

❖ For Single use.
❖ The maximum suction time should not exceed 15 seconds.
❖ If suctioning is required again, repeat the process after a brief pause to allow the airway to recover and prevent excessive irritation.
❖ If necessary Re-oxygenate the patient after suctioning, and continue to ventilate for two minutes and then suction again.
❖ Choose the suitable size of suction catheters.
❖ Rinse the catheter with water or saline to prevent obstructions of the catheter.
❖ The catheter size must never exceed 50% of the internal diameter of the endotracheal or tracheostomy tube.
❖ Discard after single use, Reusing can be associated with Cross infection, Device Malfunction and Reactions to endotoxins as sterilization will not inactivate toxins produced by the breakdown of Gram-negative bacteria even if the bacteria themselves are killed.

- ❖ DO NOT re-sterilize and /or reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factors, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.
- ❖ The product should be used only by qualified doctors or paramedics who are experienced and have a thorough understanding of the clinical and technical aspects of product.
- ❖ Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability.
- ❖ Contamination and / or limited functionality of the device may lead to injury, illness of the patient.
- ❖ Ensure that the suction catheter is completely removed from the tracheal tube before cutting the tracheal tube to length. Failure to do so may result in catheter damage, fragment retention, airway obstruction, or injury to the patient.
- ❖ Storage up to 30º C ± 2℃, avoid excessive heat, protect from direct sunlight and moisture.
- ❖ The device should be disposed as per the safe disposal instructions as described in the instructions for use.
- ❖ Ultramed will not assume any responsibility in case of any incidental or consequential damages resulting from reuse of the product.

- ***Precautions:***

- ❖ Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions.
- ❖ Failure to do so may result in complications. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged.
- ❖ The device is for Single Use Only.
- ❖ Do not use if package is open or damaged.
- ❖ Check the integrity and functionality of the suction catheters before use.
- ❖ Use the product immediately after opening the individual blister packing.
- ❖ Do not re-sterilize.
- ❖ This device does not contain phthalates (DEHP FREE); as marked.
- ❖ Determine patient's condition and vital status During device application / Operation.
- ❖ Never apply suction while inserting the catheter, as this can damage the airway
- ❖ If suctioning is required again, repeat the process after a brief pause to allow the airway to recover and prevent excessive irritation.
- ❖ Avoid prolonged suctioning to prevent hypoxia
- ❖ In patients with pneumothorax and emphysema, careful consideration and appropriate technique (such as suction pressure should be kept low, and it should only be applied for short periods) are critical to avoid worsening the patient's condition.

- ❖ Conduct procedure under strict surgical protocol and ensure complete asepsis.
- ❖ Destroy the device after single use as bio-medical waste as per applicable laws.
- ❖ Do not use the device after the Expiry Date

- ***Risks Associated with reuse***

Re-use of the device may create a potential risk to the patient, including contamination and/or impairment of the device function.

- ***Potential Complications / Risks:***

- Mechanical Trauma to the airway,
- Bleeding
- Hypoxia, Hypoxemia
- Cardiac arrhythmias
- vasovagal stimulation.
- Aspiration
- Pain, Distress, Discomfort
- Laryngospasm Bronchospasm, Respiratory arrest
- Atelectasis
- Infection
- Lesions in tracheal mucosa
- Ventilator Associated pneumonia
- Kinking
- Obstruction of the lumen, debris or fluid in the lumen.
- Fracture of the shaft of the suction catheter.
- Leakage.

- ***General Instructions:***

To be used by an expert qualified medical professional. Use maximal sterile barrier precautions during usage. Dispose the device after use as bio-medical waste as per applicable laws.

- ***Conditions of Handling, Preservation and Storage:***

- ❖ Not more than 5 cartons on each other.
- ❖ Nice Ventilated place.
- ❖ Out of Sunlight.
- ❖ Storage at room temperature up to 30°C ± 2°C.
- ❖ Humidity: RH 65% (± 5)

- ***Safe Disposal of single-use medical devices:***

- ❖ adopt adequate precautions for the elimination and disposal of the device and comply with the provisions of the laws in force on biologically hazardous waste.
- ❖ Single-use devices must be segregated from other reusable devices and, should not be returned to a Decontamination facility for reprocessing. Once discarded (used or unused) medical devices are considered to be special waste and should be managed as healthcare (clinical) waste. All medical devices that are to be

disposed of, must in accordance with Health and Safety, Carriage of Dangerous Goods and Waste Regulations.

- ❖ Discarded devices should be placed in UN-type approved waste containers suitable for clinical waste (UN 3291); these should be rigid and puncture-proof. In general devices other than sharps should not be placed in sharps boxes as sharps waste is treated and disposed of in a different manner. Guidance on the type and color of the container should be sought from the Board Waste Management Officer. rigid water-tight containers are used for waste requiring incineration in a suitably permitted or licensed facility.

- ***Method of sterilization:***
- Sterilized Using Ethylene Oxide
- ***Shelf life:***
- 5 years (from the date of manufacturing)

Basic UDI: 622300425SCC2001QV

Reporting of incident to Manufacturer & Competent Authority:

- For providing feedback on this product write to shady@ultramedumic.com
- In case of any serious incident occurred, please report it to the Ultra for medical products (ultramed) Co (U.M.I.C) S.A.E and/or its Authorized Representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Details of symbols used in labels:

Symbol	Meaning
EU REP Obelis SA 53 Bd. Général Wahis B-1030 Brussels,Belgium Phone : 32.2.732.59.54 Fax : 32.2..732.60.03 E-mail: mail@obelis.net www.obelis.net	EU REP
CE 2803	CE Mark with notified body number 2803
STERILE EO	Sterilized by Ethylene Oxide
	For Single Use Only
LOT	Lot No.
	Date of Manufacturing
	Use by / Expiry date
REF	Catalogue No.
	Non- Pyrogenic
MD	Medical Device
UDI	Unique device Identifier
	Don't use if package is not intact
	Manufacturer's address
RHT NON-DEHP	Phthalate-Free
	Read Instructions for Use
2 STERILIZE	Not to be re-sterilized
30 °C ± 2	storage at room temperature up to 30 °C ± 2°C
LATEX	Latex Free
	Cautions

Symbol	Meaning
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „This way Up“
	Symbol for „handle with Care“
	Recycle
	Don’t put more than 5 cartons upon each other

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Assiut Factory: Part no. (304:310) and part no. 312 - Arab El Awamer - Industrial zone – Abnoub - Assiut, Egypt.
Tel: 088/4960500 – 4960600 & **Fax:** 088/4960400 & **Mob:** 0101558853
Cairo Head Office: 64, Nakhla El Motaiy Triumph Square Heliopolis **Tel:** 022/4171621-4143794 & **Fax:** 022/4171613 & **Mob.** 0123988200
Assuit Office: 23, July Str. **Tel:** 088/2364111 – 2364222 & **Fax:** 088/2334964 & **Mob. :** 0123988202
Alexandria Office: 212Abd El salaam Airef Str, Luran **Tel:** 03/5856202– 5856458 & **Fax:** 03/5828988& **Mob:** 0123948666
E-mail: info@ultramedumic.com , shady@elaggargroup.com **Website:** www.ultramedumic.com