ULTRA FOR MEDICAL PRODUCTS CO.

INSTRUCTION FOR USE FOR STERILE YANKAUR SUCTION SET (YANKAUR CROWN) TUBE AND HANDLE

Product Name	:	Yankaur suction set (yankaur crown) tube and handle
Brand Name	:	Ultramed Yankaur suction set (yankaur crown) tube and handle
Manufacturer's Name	:	Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E
Manufacturer's Address	:	Part no. (304 : 310) and part no. 312 - Arab El Awamer - Industrial zone – Abnoub - Assiut, Egypt.

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

- The Yankaur suction set (yankaur crown) tube and handle is suctioning tool used in medical procedures. It is typically a firm plastic suction tip with a large opening surrounded by a bulbous head and is designed to allow effective suction without damaging surrounding tissue. This tool is used to suction oropharyngeal secretions in order to prevent aspiration. A Yankaur can also be used to clear operative sites during surgical procedures and its suctioned volume counted as blood loss during surgery.
- The Yankaur suction consist of Yankauer suction set, Connecting tube, PVC tube and Suction handle

Material Used:

- Poly Vinyl Chloride [PVC]
- ABS (Acrylonitrile Butadiene Styrene) Compound

Intended purpose:

A device that intended for the aspiration of fluids and/or particulate matter, or to assist in some intervention. It is intended for short-term use.

- **Variants:**

Ref Code	Type
9008-01	Yankaur Suction Set (Standard Tip)
9008-02	Yankaur Suction Set (Crown Tip)
9008-03	Yankaur Tube
9008-04	Yankaur Handel

Clinical Indications:

- Removing respiratory secretions when the patient is unable to.
- Assisting a patient that is vomiting while seizing or unconscious.
- Clearing blood from the airway.
- Removing a foreign substance from a patient's windpipe and/or lungs (pulmonary aspiration)
- Clear operative sites by aspiration of secretions in surgical procedures as blood.
- General suctioning in emergency and critical care situations.

Contraindications:

Not to be used in patients with known hypersensitivity to any of the materials used.

Device Limitations:

Yankaur suction tubes used in short-term uses.

Patient Target Group:

Infants, Paediatrics and Adult

Replacement Frequency:

If contamination is suspected before use or during use

Intended User:

- To be administered by an expert qualified medical professional, Skilled Or Trained Personnel (In-Charge)

Clinical benefits:

- Effective removal of dental plaque
- maintain the integrity of oral tissues
- reduce the risk of contaminating the patient’s environment
- shorter intubation time
- Easier to handle
- Higher success rate
- Suction force is more Powerful.

Use Environment:

- Hospital, Emergency Room, Critical care room, intensive care units and those requiring Nelaton catheter on outpatient basis.

Life time of device:

- 5 Years

Sterility status and Method of sterilization:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused Device

Information on medical device intended to be used with other devices:

- Yankaur suction set (yankaur crown) tube and handle connected with suction source through connector which designed as per EN ISO 80369-1:2020 and EN ISO 80369-20:2015

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.

Instruction for Use:

- Wash up and scrub hands and preferably use pre-sterile protective
- glove.
- Peel opens the pack and removes the device aseptically.
- Attach suction handle with sufficient tubing near the operation field,
- on the drape.
- Connect the other end of the tube with suction line.
- Activate the suction by closing the hole on suction handle with the
- help of thumb or index finger.
- Suck little sterile water after each suction to keep the whole system
- clean and prevent any possible blockage.
- Discard the device after single use.

Warnings:

Hypoxia can be profound from occlusion, interruption of oxygen supply, and prolonged suctioning. Mucosal trauma, physical injuries,

- ***Precautions:***
  - Prior to using read entire instructions for use.
  - Failure to do so may result in severe patient injury.
  - Ultramed disclaims any responsibility for possible consequences from improper use.
  - Do not clean or Re-use the device,
  - For single Patient use only.
  - Discard after Single use.
  - The product should be used immediately after opening the packing.
  - Do not use with a stylet or guide wire
  - Do not use the device after expiry Date mentioned on the Label.
  - If the patient is sensitive or allergic to PVC, do not use the device.

- Single use, the use by more than one patient may cause a cross-infection.
- Do not use the product if it is dirty or evidently deteriorated.
- read instruction before use.
- check expiry date prior to use.
- visually inspect and carefully check the product & packaging before use.
- the product is guaranteed non-toxic, sterile and non-pyrogenic if the package has not been opened or damaged.
- the product should be used by trained person.
- Do not use if package is open or damaged.
- Discard after single use.

  Potential Complications / Risks: potential complications related to device malfunctions and human error underscore the importance of proper training, maintenance, and adherence to best practices. This complications include:

- Mechanical Trauma to the airway,
- Bleeding
- Hypoxia, Hypoxemia
- Cardiac arrhythmias
- vasovagal stimulation.
- Vomiting
- Aspiration
- Pain, Distress, Discomfort
- Laryngospasm Bronchospasm, Respiratory arrest
- Atelectasis
- Infection
- Lesions in tracheal mucosa
- Ventilator Associated

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

Conditions of Handling, Preservation and Storage:

- Not more than 5 cartoons on each other.
- Nice Ventilated place.

- Out of Sunlight.
- Suitable temperature from 5º C to 32º 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)

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
EC 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
PHT NON-DEHP	Phthalate-Free
	Read Instructions for Use
2 STERILIZE	Not to be re-sterilized
5c 32c	storage temperature from 5 °c to 32 °c
	Cautions
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „handle with Care"

Symbol	Meaning
	
	Recycle
	Don’t put more than 5 cartons upon each other
	Latex Free

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