IFU of Yankauer Handle with connecting tube

Manufactured by Mais India Medical Devices Pvt. Ltd.

General Device Description: The device Yankauer Handle with Connecting Tube includes an elongated suction tube having a connector at the both ends distal and proximal. The proximal end of the suction tube is configured to connect to a handle and distal end connects to Yankauer suction device for the use of suctioning body fluid during operation on thoracic cavity or abdominal cavity.

The device Yankauer Handle with Connecting Tube is used in an aseptic environment. The use of the product is restricted to a qualified doctor or a paramedic.

Product Name: Yankauer Handle with Connecting Tube

Brand Names:, (1) Yankur Suction Set (2) Mais Suction Set

Variants:
1. (Standard Tip)
2. (Crown Tip)

Intended Use:
Yankauer Handle with Connecting Tube is intended for the use of suctioning body fluid in combination with suction apparatus during operation on thoracic cavity or abdominal cavity.

Material of construction:
Polyvinyl Chloride (PVC) & Polyvinyl Chloride (Rigid)

Indications:
Yankauer suction set purposive for the suction of blood debris and body fluid during surgery.

Contra-indications:
·Product should not be used in patients with known Hypersensitivity to any of the materials used.
·The device is not suitable for use with infant and pregnant women if device label does not claim DEHP-free.
·If "DEHP Free" is not claimed on the unit pack of device it means, the device should not be considered as Phthalates free during intended use.

Intended Patient Population:
All Patient age groups such as – Neonates, Paediatrics & Adults
The Yankauer suction set is suitable for any age group patient, requiring effective suctioning of fluids or obstructions to ensure safe and effective medical care.

Intended User:
Qualified doctor or a paramedic

Use environment:
Proper healthcare setup

Size specifications and color code:

Size Specification
160cm
200cm
250cm
300cm
380cm

Instructions for use:
·Check the integrity and expiry of the product.
·Remove the product from package using aseptic technique.
·Fix the handle to the one end of the tube.
·Fix other end of tube on suction pump.
·Close vacuum control window by thumb.
·Insert tip of handle in operative body part and let it remove secretion by sucking.
·Vacuum can be controlled by vacuum control window on regular interval.

Intended Clinical Benefits to the patients:
·Assists in controlling bleeding during oral surgeries and invasive procedures.
·Ensures optimal treatment outcomes and reduces complications risk, such as excessive blood loss or the formation of blood clots.
·By removing blood from the surgical site, the suction allows for better visualization.
·Used to suction oropharyngeal secretions in order to prevent aspiration.
·Can also be used to clear operative sites during surgical procedures and its suctioned volume counted as blood loss during surgery.

Clinical Safety:
·Moulded Yankauer suction handle with flexible kink resistant tube.
·Suitable for use with or without vent control facility.
·Vent port is closed with tight fit sleeve, which can be removed by small incision to shift to vent control system.
·Biocompatible products,
·our device is a single use device,
·our product is non-toxic, sterile & non-pyrogenic.

Performance characteristics:
·Yankauer handle with connecting tube is made of medical – grade biocompatible polycarbonate. Yankauer Handle with Connecting Tube is intended for the use of suctioning body fluid in combination with suction apparatus during operation on thoracic cavity or abdominal cavity Used for removal of secretions and blood peri-operatively by providing unobstructed suction during prolonged use.
•Soft flexible adaptors at both ends of the tube provide safe grip to the handle as well as suction source.

Accessories which can be used with the device:
Yankauer Handle with connecting tube shall be used with suction device (suction pump) to perform its claimed intended purpose.

Warnings:
1. The use of this product is restricted to a qualified doctor or a paramedic
2. Read instructions before use.
3. MAIS INDIA disclaims any responsibility for possible consequences resulting from improper use.
4. The product should not be reprocessed.
5. Visually inspect and carefully check the product and packaging before use.
6. Improper transport and handling may cause structural and/or functional damage to device or packaging.
7. The product is non-toxic, sterile & non-pyrogenic.
8. Do not Clean or resterilize. For single use only. Discard after use.
9. Re-use of single-use devices creates a potential risk.
10. If the device is reused, then it may cause bacterial infection to the patient, and also may lead to contamination and/or impairment of functional capability which may in turn lead to injury to the patient.
11. If there is any change in expected performance of the device or in case of any malfunction the device should be immediately removed & sent back to supplier for analysis.
12. Store in a cool & dry place.
13. Do not expose to heat or direct sunlight.
14. The product should be used immediately after opening the packaging.
15. Do not use product after expiration date
16. Use of product after extended period of time may cause infection.

Cautions:
•Discard after single use.
•Do not use if the package is damaged.

Limitations:
•Improper transport and handling may cause structural and/or functional damage to device or packaging.

Potential Side Effects:

There is No any Serious Adverse Event reported from users end.

Disposal Instructions:

The unused device can safely be disposed of as normal hospital waste in a 'Sharps' container. The used device should be disposed of as 'hospital contaminated waste' - typically incinerated or as per safe hospital practices as improper disposal can lead to bio-hazard.

Duration of use:

Short Term Duration (Normally intended for continuous use of 60 minutes)

Storage Conditions:

Store in a Cool & Dry Place. Keep away from sunlight.

Temperature: +10ºC to +40ºC

Humidity: 50 ± 10%

Shelf life:

5 Years

Lifetime:

Once used started, normally intended for continuous use of 60 minutes.

Type of Sterilization:

ETO sterilization.

Notice to Users and/ or Patients:

Any serious incident that has occurred in relation to the device, should be reported to the Manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Date of manufacture (Indicates the date when the medical device was manufactured)
STERILE EO	Sterilized using ethylene oxide (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)	LOT	Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)	CE 0123	CE Mark
	Non-pyrogenic (Indicates a medical device that is non- pyrogenic)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)	EC REP	Authorized representative in the European Community / European Union (Indicates the authorized representative in the European Community / European Union) OBELIS S.A. Boulevard Général Wahis 53, 1030 Brussels, Belgium Contact Number: +32(2)73 25 954 Email ID: regulatory@obelis.net Website: www.obelis.net
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com
STERILE EO	Single sterile barrier system (Indicates a single sterile barrier system)	IN	Country of manufacture (To identify the country of manufacture of products)
UDI	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)	MD	Medical device (Indicates the item is a medical device)
60% 40%	Humidity limitation (Indicates the range of humidity to which the medical device can be safely exposed.	40°c 10°c	Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.
	Refer to instruction manual/ booklet		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
REF	Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)		This way up

Symbols	Title of the Symbol	Symbols	Title of the Symbol
NPT DEHP	Indicates product that does contain the phthalate plasticizers DEHP.	PHT DEHP	Contains or presence of phthalate plasticizers DEHP

Manufactured by:
Mais India Medical Devices Pvt. Ltd.
525-P, Sector-37, Pace City-II,
Gurgaon, Haryana-122001 (INDIA)

EC REP
Obelis S.A.
Boulevard Général Wahis 53, 1030 Brussels, Belgium.

EDITION: 02, REV.:- 00_05.08.2025