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CLOSED SUCTION SYSTEM

Instructions for Use

READ ALL PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE

INTENDED USE

The SPICTRA CLOSED SUCTION SYSTEM used for suction of fluids getting collected in the airway path during long term ventilation.

INDICATIONS

The SPICTRA CLOSED SUCTION SYSTEM is indicated for use in airway management system along with the ventilator.

DESCRIPTION

The SPICTRA CLOSED SUCTION SYSTEM is supplied sterile & non - pyrogenic. It helps in Airway management system, enabling fluid suction from the patient's intubated endotracheal tube, without ventilator disconnection thereby maintaining arterial oxygen saturation levels, and with no contact of secretions during suction. Double swivel patient end connector offers convenience of 360⁰ rotatable. This IFU is applicable to all the models of Closed suction system manufactured by MediHub Sciencetec Private limited. The isolation chamber has the less internal volume of 11787.893 mm^3 ± 2 percent (0.0117 liters) which reduce the volume of rebreathed gases.

DEVICE COMBINATION

Endotracheal suctioning is a procedure that may constitute a risk factor for ventilator-associated surgeries, and it is performed with a closed suction system. Closed suction system is used to enhance clearance of respiratory tract secretions, improve oxygenation, and prevent atelectasis.Wherein after surgery the secretion is collected by inserting a catheterinto the airways without disconnecting the patient from the ventilator.

Connect patient end Double swivel Elbow connector with ET Tube (Or Tracheotomy tube), Connect breathing tube connector with the ventilator. Connect the other end of Closed suction system (negative pressure end connector) with Suction unit.

The vacuum is controlled by connecting the closed suction system with the Suction unit.

"Our products are designed such a way that match the product specification of the connected devices & are compatible with the devices used ".

PRECAUTIONS

- For single use only. Do not re-sterilize or reuse it.

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- Do not use if package is open or damaged.
- The operator should be well trained in every procedure described in "instructions of use"
- Follow your theatre SOP for the usage procedures.
- The device is used in combination with other medical device. The surgeon can use MediHub's or other company's combination device. The surgeon using the device in combination with MediHub product or other company's product should be well trained & experienced for proper use of the device.

WARNING

1. Bradycardia/desaturation may occur from either inserting the catheter too slowly or using a large catheter which occludes the internal lumen of the Endotracheal tube. Close observation of the patient's oxygen saturation and heart rate is required during the procedure.
2. Limited duration of suctioning, no longer than 5–10 sec per pass.
3. Forceful withdrawal of the catheter may pull the catheter tip out of the seal located near the irrigation port. This will cause the bag around the suction catheter to inflate and sometimes pulse with air. Ventilation still occurs, but the peak pressures will be somewhat reduced and the patient may deteriorate. Fixation of this problem by simply feeding the catheter back through the seal can be performed.
4. Accidental extubating may occur if the Endotracheal tube is not properly supported during withdrawal of the catheter.
5. The use of closed suction catheters should be considered part of a Ventilator-Associated Pneumonia (VAP) prevention strategy, and they do not need to be changed daily for infection control purposes. The maximum duration of time that closed suction catheters can be used is recommended for 72 hours.
6. Do not trim or cut the endotracheal tube (not supplied) while the closed Suction Catheter is attached, otherwise the catheter may also be cut and that portion of the catheter may be aspirated into the lower respiratory tract of the patient and may cause death or serious injury.

CONTRAINDICATIONS

- This device used for any other purposes than for the indicated use is the responsibility of the user.
- Do not use 65 cm catheters on tracheostomy patients. Mucosal damage may result.

SETUP OF CLOSED SUCTION SYSTEM

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1. Select appropriate size catheter. Use aseptic technique.
2. Cut open the cover and inspect for any damages. Device should not be used, if any damages found.
3. Connect patient end Double swivel Elbow connector with ET Tube (Or Tracheotomy tube), Connect breathing tube connector with the ventilator. Connect the other end of Closed suction system (negative pressure end connector) with Suction unit.
4. Set the appropriate vacuum in the suction unit.
5. If any secretions to be removed open the isolation chamber control valve, push the suction catheter into the lung cavity and press the thumb control valve to remove the secretions.
6. Limited duration of suctioning, no longer than 5–10 sec per pass.
7. Use the irrigation port for flushing secretions & catheter cleaning.
8. Place the stickers on suction valve to know the changing frequency.
9. The Closed Suction System set is used for 72 hours with a day sticker to identify the replacing day.
10. Change more frequently if catheter becomes heavily soiled during use.

DISPOSAL METHOD

The used device must be disposed of as per local regulatory requirements and corresponding hospital disposal procedures for biohazard materials.

CONNECTION OF DEVICES

The SPICTRA CLOSED SUCTION SYSTEM is connected with a Suction unit providing a vacuum level of -80 to -120 mmHg for adults & -80 to -100mmHg for infants and children.
The SPICTRA CLOSED SUCTION SYSTEM is connected to ventilator circuit & Endotracheal tube.

STERILITY

Three years from the sterilization date. Sterile if the package is not damaged.

Manufacturer Information

Medihub Sciencetec Private Limited.,

Plot no.4, NH-7, MMDA Industrial Estate, Maraimalainagar-603 209 Tamilnadu, India.

Telephone No.: 044-47400484

Website: www.spictra.com

Email: enquiry@spictra.com

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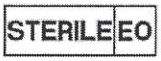
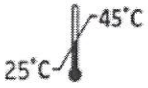
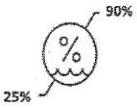
Mfg L.No: MFG/MD/2021/000327

Information on Symbols

	**Do not resterilize** Indicates a medical device that is not to be resterilized.		**Use-by date** Indicates the date after which the medical device is not to be used
	**Consult Instructions for Use** Indicates the need for the user to consult the instructions for use.		**Do not re-use** Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	**Sterilized using ethylene oxide** Indicates a medical device that has been sterilized using ethylene oxide.		**Batch Code** Indicates the manufacturer's batch code so that the batch or lot can be identified.
	**Temperature Limits** Indicates the limit of temperature to which the medical device can be safely exposed.		**Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed
	**Authorized Representative in the European Union** Indicates the Authorized representative in the European Union. **MEDDEVICES LIFESCIENCES B.V** Keizersgracht 482, 1017EG Amsterdam, Netherlands Email: nk@meddevices.net Phone: +31202254558 Web site: www.meddevices.net		**Keep away from Sunlight** Indicates a medical device that needs protection from light sources.

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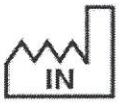
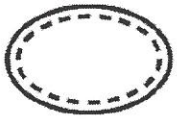
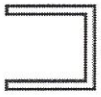
	**Date Of Manufacture along with Country of manufacture** Indicates the date when the medical device was manufactured.		**Caution** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	**Manufacturer** **Medihub Sciencetec Private Limited.,** Plot no.4, NH-7, MMDA Industrial Estate, Maraimalainagar-603 209 Tamilnadu, India. **Telephone No.:** 044-47400484. **Website:** www.spictra.com **Email:** enquiry@spictra.com		**Single sterile barrier system with protective packaging inside** Indicates Single sterile barrier system with protective packaging inside
	**Fluid Path** Indicates the presence of a fluid path		**Do not use if package is damaged** Indicates a medical device that should not be used if the package has been damaged or opened.
	**Medical Device** Indicates the item is a medical device		**Keep dry** Indicated a medical device that needs to be protected from moisture
	**Non-pyrogenic** Indicates a medical device that is non-pyrogenic		**Model number** Indicates the model number or type number of a product.

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