VACUUM-POWERED BODY FLUID SUCTION APPARATUS
(CHEST / THORACIC DRAINAGE SYSTEM)

Instructions for Use

READ ALL PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE

INTENDED USE

Chest / Thoracic Drainage System and its Accessory Bedside Vacuum Controller is closed system working under regulated vacuum to collect the intra pleural drainage after cardiopulmonary or thoracic surgery.

INDICATIONS

Device used to remove pleural effusion, blood, or pus after cardiopulmonary or thoracic surgery.

DESCRIPTION

This product is used to collect the wounded blood from the chest cavity after closing the sternum. It is available in single, double and triple chambers. Overflow design helps in using the Chest / Thoracic Drainage System for both adult and pediatric patients. This can be used for maximum of 7days, as recommended by doctor, it can even be removed as per the recovery of the patient. There is no clinical significance of the duration of use. This IFU is applicable to all the models of Chest / Thoracic Drainage System manufactured by Medihub Sciencetec Private limited.

DEVICE COMBINATION

The device are used in the Post surgery process. Wherein after surgery the waste blood and fluid is collected by inserting a drain tube in between the pleural space by the chest drainage system which is completely sealed chamber.

A patient may require a chest drainage system any time the negative pressure in the pleural cavity is disrupted.

The vacuum is controlled by interlinking the chest drain system with a Bedside vacuum controller which maintains the atmospheric pressure by the water filled to a specific level.

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

PRECAUTIONS

1. Do not overfill the air leak monitor above the fill line.
2. Suction source should be set at -5332.89 Pa (-40mmHg) to-26664.47 Pa(-200mmHg).
3. Must be used with adequate accessories.
4. Ensure that Chest / Thoracic Drainage System connected properly to the connections before the start operation and also check it routinely that Chest /Thoracic Drainage System is compatible with the connectors or accessories.
5. Patient tube connections, water seal, and suction control chamber should be checked regularly to confirm proper operation
6. Chest drain must be kept below the patient's chest in an upright position.
7. Replace chest drain if damaged or when collection volume meets or exceeds maximum capacity.
8. Volume of the collected drain fluid in the inflow chamber can be measured using the yellow level sticker and in the overflow chamber can be measured with white level sticker.
9. Patient tube connections, air leak monitor, vacuum indicator, suction regulator and bellow should be checked regularly to confirm proper operation.
10. Pre-packaged sterile fluid for chest drainage use only.
11. Do not use if device or package is damaged.
12. Users should be familiar with thoracic surgical procedures and techniques before using a chest drain. To be used by skilled professional only.

WARNING

1. Do not obstruct the positive pressure release valve located on top of drain. Occlusion may cause tension pneumothorax or may compromise respiratory function.
2. Do not manually depress high negativity vent when patient is on gravity drainage or when suction is not operating. This may open the pleural space to atmospheric pressure and compromise respiratory function.
3. Do not separate patient tube in-line connector prior to clamping off patient tube first. Doing so may result in opening the pleural space to atmospheric pressure and compromise respiratory function.
4. Do not keep patient tube clamp closed during drainage collection or patient transport. Doing so will prevent drain operation and may compromise respiratory function if fluid drainage is stopped or an active pneumothorax is present.
5. For single patient use only. Do not reuse, reprocess or re- sterilize. Reuse, reprocessing or re- sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
6. Connect it to thoracic drainage catheter.
7. Chest / Thoracic Drainage System when connected to Glass bottles for controlling vacuum can cause infections to patient as well as surrounding compared to when Connected to sterile Bedside vacuum controller can be aseptic.

CONTRAINDICATIONS

? The device should not be used without prior to water filling so as to eliminate the occurrences of pneumothorax.

INSTRUCTION FOR USE

1. Use aseptic technique
2. Open the cover and inspect for any damage
3. Device should not be used if any damage.
4. The product must be used only by trained and qualified medical personnel.
5. Remove fill vent port or cap. Deliver sterile water from syringe into chest thoracic drainage system fill port continue to fill port till the water fill up to the mark fill specified in caution sticker, there by establishing water seal. Close the fill vent port with its cap model M3D, M5D, M6D, M14D.
6. Similarly fill sterile water in two ports of M8D model.
7. If not inserted the Drain and vacuum lines, remove the Drain and Vacuum port caps. Take the Soft Translucent tube pack and Connect the vacuum and Drain line tube. The tube should be inserted over all these preparations in the ports till the bottom.
8. Ensure that the springs are in place
9. Connect free end of the vacuum tube to the centralized vacuum line or Spictra Bed side vacuum CDS line.
10. Now the Device is ready for use. Adjust the vacuum source to recommended settings.
11. Connect the drain tube to thoracic drainage catheter.
12. This tubing line can be connected to the thoracic catheter through a barbed connector which is capable of connecting / fitting to any type of thoracic connector.

SETUP OF CHEST AND THORACIC DRAINAGE SYSTEM

Step 1. Fill BVC (Bedside vacuum controller- M4 BV) to 50% of the total capacity with water through atmosphere line (In case of M5 BV use water filling port).

Step 2. Fill CDS (Chest / Thoracic Drainage System) with Sterile / saline water for the quantity as mentioned in the caution sticker pasted on the device through "fill/vent" port.

Step 3. Connect Patient Tube to Patient – Connect drain line from "Drain" port to patient prior to initiating suction. (In case of M14 D connect one end of the drain line first to "Drain" port of the device and then other end to the patient).

Step 4. Connect Suction source to BVC – Attach suction line to "wall suction" port on top of BVC device.

Step 5. Connect Bed side vacuum control with Chest / Thoracic Drainage System – Connect suction line from "vacuum Line" port on the Bed side vacuum control device to "CDS line" port on the Bed side vacuum control device. (In case of M14 D connect one end of the suction line first to CDS device "vacuum line" port and other end to the Chest / Thoracic Drainage System line port on the Bed side vacuum control device.)

Step 6. Turn Suction Source On – Increase suction source vacuum to -5332.89 Pa (-40mmHg) or Higher.

DISPOSAL METHOD

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

CONNECTION OF DEVICES

Device used in connection with Bedside Vacuum Controller.

STERILITY

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

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SL. NO	MODEL	CAPACITY	DIFFERENCE IN CONSTRUCTION			DIFFERENCE IN APPLICATION
			NO OF CHAMBERS	Length of Drain / Vacuum Lines (feet)	No of ports	
1	M3 D	2 litre	Single	Drain - 4 ft Vacuum - 0.3 ft	Vacuum -1; Drain -1; Fill/Vent -1	Used for Adult only
2	M5 D	2 litre	Double	Drain -3 ft Vacuum- 4 ft	Vacuum -1; Drain -1; Fill/Vent -1	Used for both adult and Pediatric Double chamber facilitate measurement of volume below 50ml as required by pediatric patients.
3	M6 D	2 litre	Double	Drain- 5 ft Vacuum- 2 ft	Vacuum -1; Drain -1; Fill/Vent -1	Used for both adult and Pediatric Double chamber facilitate measurement of volume below 50ml as required by pediatric patients. Difference in the length of drain and vacuum line is according to the specific hospital requirement.
4	M8 D	2 litre	Triple	Drain - 5 ft Vacuum- 2 ft	Vacuum -1; Drain -2; Fill/Vent -1	Used for both adult and Pediatric Additional drain is to collect intra pleural drainage from additional cavities as required by the specific procedure
5	M14 D	2 litre	Double	Drain – 6.5 ft Vacuum- 2 ft	Vacuum -1; Drain -1; Fill/Vent -1	Used for both adult and Pediatric Provided with unconnected tubing's To measure lower volume

***Note: Bedside vacuum controller models (M4 BV & M5 BV) can be connected either to any type of Chest /thoracic Drainage System model of Spictra or other similar products available in the market.**

Manufacturer Information

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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.	STERILE EO	Batch Code Indicates the manufacturer's batch code so that the batch or lot can be identified.	LOT
Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed	90% 25%	**Temperature Limits** Indicates the limit of temperature to which the medical device can be safely exposed.	45°C 25°C
Date Of Manufacture along with Country of manufacture Indicates the date when the medical device was manufactured.	IN	**Keep away from Sunlight** Indicates a medical device that needs protection from light sources.	
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		**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 medicaldevice itself.	
Fluid Path Indicates the presence of a fluid path		**Single sterile barrier system with protective packaging inside** Indicates Single sterile barrier system with protective packaging inside	
Medical Device Indicates the item is a medical device	MD	**Do not use if package is damaged** Indicates a medical device that should not be used if the package has been damaged or opened.	

	Non-pyrogenic Indicates a medical device that is non-pyrogenic		**Keep dry** Indicated a medical device that needs to be protected from moisture
#	**Model number** Indicates the model number or type number of a product.	UDI	**Unique Device Identifier** Indicates a carrier that contains Unique Device Identifier information

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