VACUUM-POWERED BODY FLUID SUCTION APPARATUS (BEDSIDE VACUUM CONTROLLER)

Instructions for Use

READ ALL PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE

Spictra

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 as an accessory with Chest /thoracic Drainage system to control the vacuum level. It is available in 1000ml chamber. This IFU is applicable to all the models of Bedside Vacuum Controller manufactured by us.

DEVICE COMBINATIONS

The device is used in the Post surgery process. Wherein after surgery the waste blood and fluid is collected by inserting a drain tube in between the plural 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 the circuit.’’

PRECAUTIONS

1. Do not overfill the air leak monitor above the fill line.
2. Suction source should be set to-80mmHg or higher for Chest/thoracic drain regulator settings of - 5332.89Pa (-40 mmHg) to-26664.47Pa (-200mmHg).
3. Must be used with adequate accessories.
4. Ensure that Bedside Vacuum Controller connected properly to the connections before the start operation and also check it routinely that Bedside Vacuum Controller is compatible with the connectors or accessories.
5. Chest /thoracic drain must be kept below the patient’s chest in an upright position.
6. Replace Chest /thoracic drain if damaged or when collection volume meets or exceeds maximum capacity.
7. Patient tube connections, air leak monitor, vacuum indicator, suction regulator and bellow should be checked regularly to confirm proper operation.
8. Pre-packaged sterile fluid for Chest /thoracic drainage use only.
9. Do not use if device or package is damaged.
10. Users should be familiar with thoracic surgical procedures and techniques before using a Chest /thoracic drain.

CONTRAINDICATIONS

? There are no known contraindications of these products.

SETUP OF BEDSIDE VACUUM CONTROLLER

? Use aseptic technique
? Open the cover and
? Device should not be used, if any damages found.
? The product must be used only by the trained and qualified medical personnel.
? For single use only. Do not re-sterilize or reuse it.
? I fM4BV model is used fill the sterile water to appropriate vacuum level through Atoms line.
? If M5 BV model is used fill the sterile water to appropriate vacuum level through water filling port.
? Connect the vacuum source to the vacuum port. Connect the Chest /thoracic Drainage system to the Chest /thoracic Drainage system port. Adjust the vacuum source depends on the water height level.
? Now the device is ready for use.

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 chest and thoracic drainage system.

STERILITY

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

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Sr. NO	MODEL	CAPACITY	DESIGN DIFFERENCE	APPLICATION
1	M4 BV	1000 ml	Ports available –Atmos Line, Chest /thoracic Drainage system Line, Vacuum Line	For controlling the vacuum level.
2	M5 BV	1000 ml	Ports available –Atmos Line, Chest /thoracic Drainage system Line, Vacuum Line, In-addition Water filling port.	For controlling the vacuum level additional port according to the specific requirement of hospital.

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SPECIFICATION OF BVC

Housing Poly Styrene
Vacuum Port - 1/4"
CDS Port - 1/4"
Atmosphere Line - 1/4"
Water filling port - 1/2"
Capacity - 1000 ml

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

Medihub Sciencetec Private Limited.,

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Maraimalainagar-603 209 Tamilnadu, India.
Telephone No.: 044-47400484.Website: www.spictra.com
Email: enquiry@spictra.com
License Number: 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
STERILE EO	Sterilized using ethylene oxide Indicates a medical device that has been sterilized using ethylene oxide.	LOT	Batch Code Indicates the manufacturer's batch code so that the batch or lot can be identified.
25°C 45°C	Temperature Limits Indicates the limit of temperature to which the medical device can be safely exposed.	25% 90%	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed
IN	Date Of Manufacture along with Country of manufacture Indicates the date when the medical device was manufactured.		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
MD	**Medical Device** Indicates the item is a medical device		**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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