Instructions for use

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This instruction cannot be used as a manual for chest drainage technique. To learn adequate knowledge about chest drainage technique it is necessary to contact our company or authorized distributor and to acquaint with appropriate technical instructions, professional medical literature and graduate proper training under supervision of a medical doctor experienced in techniques of chest drainage. Before use, we recommend reading precisely all information included in this manual. Not being obedient to these information may lead to serious medical consequences such as patient infection, accumulation of fluid and/or air in the pleural cavity or tension pneumothorax.

Indications:

- To enable air and/or fluid evacuation by thoracic catheter from the chest cavity or mediastinum. 1.
- To help prevent air and/or fluid from reaccumulating in the chest cavity or mediastinum. To help re-establish and maintain normal intrathoracic pressure gradients.
- 3. 4.
- To facilitate complete lung re-expansion to restore normal breathing dynamics.

Description:

Three Chamber Chest Drainage Unit Thora Green III is provided as a sterile unit intended for single patient and procedure use. It consists of collection chamber (A), water seal chamber (B) and suction control chamber (C). Collection chamber is divided into 2 compartments for higher accuracy. Its total volume is 2500 ml. Water seal serves as one way valve and its design prevents seal loss in case of abrupt pressure gradient changes between right and left side of the unit. Suction control chamber (C) allows to set suction force up to maximum -25 cm H₂O

Product illustration:

- Collection chamber Water seal chamber В.

 - Suction control chamber
- C. D. Collection chamber volume scale F
- Suction force scale Patient tube High negativity relief valve J. High positive pressure relief valve

Water seal level line

- Water seal negative pressure scale
- Instructions for use:
 - Place chest drainage unit in a disposable stand provided with the unit or hang it on the patient's bed side bar using the hangers attached to the unit (M). Fill suction control chamber (C) with sterile water or saline to the prescribed level. It should be done via fill port (L). Water colour change will be observed thanks to dye added to the
 - 2. chamber. It is not recommended to fill below 5 cm H₂O indication on the scale.

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- Fill water seal chamber (B) with sterile water to the water seal level line (F). It should be done with a syringe via suction tube (K). Connect suction tube (K) (short one ended with green connector) to the controlled aspiration source or use as breather pipe if the device is used by gravity. 3. 4.
- Remove the protective cap from the multigage connector (transparent taper connector) from the patient tube and connect it to the thorax catheter of the patient. Switch suction source on (for active drainage) and increase air flow to obtain moderate bubbling in the left window of the suction control chamber (C). Water level in the suction control 5. 6. chamber determines the approximate amount of suction imposed regardless of the amount of source suction, provided that bubbling appears in the left window of the suction control
- chamber (C) 7 Suction level imposed can be changed by adding / removing water in control chamber (C). Suction level imposed expressed in cm H₂O can be read directly from the suction force scale (G) of the control chamber (C).

Additional information, warnings and precautions:

- When bubbling appears in the left window of the suction control chamber (C), the suction imposed is determined by the water level in the suction control chamber (C). As long as bubbling is present, the unit is operating at the indicated suction.
- 2 In the presence of a large patient air leak, air flow through the Thora Green III unit may be increased by increasing source suction. This will not increase suction imposed on the patient. It is The presence of a large patient at leak, an now inforgentier india Green in the patient, it is not necessary to increase water level in the suction control chamber (C) to increase air flow. Check the unit periodically to ensure that adequate suction is being applied to the unit and that bubbling in the suction control chamber (C) is present at all times. If suction setting is changed from a HIGHER level to a LOWER level, the patient negativity may remain at the higher level unless the negativity is relieved. Use the high negativity relief valve
- 3. 4.
- (I) to reduce negativity to the desired level.
- (i) to reduce negativity to the desired level.
 (ii) to reduce negativity to the desired level.
 (if gravity drainage is prescribed, the suction tube (K) should remain opened and free of obstructions to allow air to exit and minimize possibility of tension pneumothorax.
 The water seal chamber (B) serves three purposes:

 it acts as a one-way valve to allow air to exit from the pleural space,
 it serves as a manometer measuring the amount of negativity in the patient's chest cavity,
 it allows for observation of the degree of air leak.

 When bubbling persists in the water seal chamber (B): 5. 6.

- 7.
- check that all connections are secure and air tight, if there is no external air leak, air is coming from the pleural space.
- 8.
- Water seal negative pressure scale (E) is used to determine negativity in patient's chest cavity: WITHOUT SUCTION, the negativity in the chest cavity is read directly by the fluid level in the water seal negative pressure scale.
- WITH SUCTION, add the water level reading from the suction force scale (G) to the reading from the water seal negative pressure scale (E). (Example: -15 suction force scale (G) plus -10 water seal negative pressure scale (E) = -25 cm H₂O patient negativity. Bubbling must be present in the left window of suction control chamber (C), indicating suction is operative, in order to
- determine the negative pressure in the chest cavity.
- Patency of the patient's thoracic catheter can be observed as water level oscillation on the water seal negative pressure scale (E). The water level rises and falls as the patient breathes. 9.
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- Conclusions and control of the present when suction is operative, the lung is fully expanded, or the tubing is blocked or kinked. Oscillations may not be present when suction is operative, the lung is fully expanded, or the tubing is blocked or kinked. Oscillations may not be present with mediastinal drainage. High positive pressure relief valve (J) opens with increases in positive pressure, preventing pressure accumulation. WARNING: Do not obstruct the high positive pressure negativity. Open the cap and depress the button to relieve negativity. Air will enter the unit and the water level in water seal will drop. Release the button when desired level of negativity, as indicated by water level in water seal negative pressure scale (E), has been attained. 11.

WARNING: Stripping or milking of the patient tube (H) can cause excessive negativity. Use the high negativity relief valve (I) to restore negativity to prescribed levels. CAUTION: if suction is not operative, or if operating on gravity drainage, depressing the high negativity relief valve (I) can reduce negative pressure within the collection chamber (A) to zero (atmospheric pressure) with the resulting possibility of a pneumothorax. Self-sealing diaphragm is provided at the back of water seal chamber (B) to adjust the fluid level. Sterile water or saline may need to be added due to evaporation. Fluid may need to be

- 12. withdrawn if the chamber is overfilled. To adjust water seal level, disinfect diaphragm and use a syringe with an 18 gauge (1,24 mm) or smaller needle. Angle the needle downward to withdraw fluid.
- 13. When drainage reaches 2500 ml, the unit is filled to capacity. Replace the unit. When changing the unit, maximum speed can be achieved by making ready a new unit by following the setup and operating instructions.
- A self-sealing diaphragm is provided in the back of the collection chamber (A) for taking samples of patient drainage. Disinfect diaphragm and use an 18 gauge (1.24 mm) or smaller needle. 14. attached to a syringe, for withdrawing samples. Disposable water resistant floorstand is provided for each unit. Unfold it, place on the flat surface with slots up and insert unit from the top into the slots
- 15.
- Two hangers (M) are located at both sides of the unit. They may be used to hang the unit at the side bar of the patient's bed. If necessary, two hangers (M) may be connected with each 16. other to form a carrying handle.
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- Front panel may be used as a marking surface. Use pen, marker or pencil. If any change of suction level is prescribed it is necessary to change water level in the suction control chamber (C). 18.
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- Use immediately after opening. Check all the connections for tightness after drainage has started. Use adhesive plaster to seal them if necessary. 20.
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- Water level in the suction control chamber (C) should be examined successively and eventually filled up due to evaporation. Collection chamber volume scale (D) is for rough orientation only. If diagnosis or therapy needs to be taken based on the readings it is recommended to use additional device with measuring 22. function for accurate volume reading. It is strictly forbidden to use patient tube (H) or suction tube (K) as a holder for the device. It could lead to water seal lost and danger to the patient The collected content of collection chamber (A) should not be used for reinfusion.
- 23.
- 24
- 25 Chest tubes should not be clamped except temporally when changing chest drainage unit. In the event of air leak, clamped chest tubes could lead to tension pneumothorax. Keep the chest drainage unit minimum 50 cm below the patient's chest level at all times.
- 26. 27
- Avoid loops in the patient tubing Caution should be used when the possibility for exposure to blood or body fluids exists. Follow hospital policy regarding the use of protective wear. 28.
- Monitor collection chamber (A). To avoid overflow, replace the unit before exceeding the fill capacity of 2 500 ml indicated by the volume graduation (D) printed on the collection chamber (A). Chest drainage unit requires appropriate disposal after use in accordance with all applicable local regulations including, without limitation, those pertaining to human health and safety and 29 30. the environment
- This product is intended for single patient and procedure use. Resterilization, reuse, modification may lead to serious consequences with death of patient included. 31.
- 32 Product is intended to be used exclusively by qualified medical staff under physician's control.





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