

STERILE EO



PLEUR-EVAC[®]

INFANT CHEST DRAINAGE UNIT

Instructions for Use
PLEUR-EVAC[®]
Infant Chest Drainage Unit

Instruções de Uso
PLEUR-EVAC[®]
Unidade de Drenagem Torácica para Recém-Nascido

Mode d'emploi
PLEUR-EVAC[®]
Unité de drainage thoracique pour nouveau-nés

Οδηγίες Χρήσης
PLEUR-EVAC[®]
Μονάδα θωρακικής παροχέτευσης για παιδιά

Gebrauchsanleitung
PLEUR-EVAC[®]
Thorax-Drainagegerät für Säuglinge

Bruksanvisning
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Thoraxdränageenhet för spädbarn

Istruzioni per l'uso
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Unità per drenaggio toracico neonatale

Käyttöohjeet
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Vastasyntyneen rintaontelon tyhjennysyksikkö

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Unidad de drenaje torácico para uso en lactantes

Bruksanvisning
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Thoraxdrenasjesystem til spedbarn

Gebruiksaanwijzing
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Thoraxdrainage-unit voor zuigelingen

Brugsanvisning
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Thoraxdrænenhed til spædbørn

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INFANT CHEST DRAINAGE UNIT



- REF A-8020-08L Latex
REF A-8020-08LF Latex Free

PRODUCT DESCRIPTION

The PLEUR-EVAC[®] Infant Chest Drainage Unit is provided as a sterile unit intended for single patient use. These instructions will address the set-up and operation of the PLEUR-EVAC Infant Chest Drainage Unit.

INDICATIONS FOR USE

The PLEUR-EVAC Chest Drainage Unit is indicated:

- To evacuate air and/or fluid from the chest cavity or mediastinum
- 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
- To facilitate complete lung re-expansion to restore normal breathing dynamics

WARNINGS

1. The collected contents of the PLEUR-EVAC Unit should not be used for reinfusion.

2. Chest tubes should not be clamped except when changing the PLEUR-EVAC Unit. In the event of a patient air leak, clamping chest tubes could lead to a tension pneumothorax.

CAUTIONS

1. Keep the PLEUR-EVAC Unit below the patient's chest level at all times.
2. Avoid loops in the patient tubing.
3. Caution should be used when the possibility exists for exposure to blood or body fluids. Follow hospital policy regarding the use of protective wear.
4. Monitor the PLEUR-EVAC collection chamber. To avoid overflow, replace the unit before exceeding the fill capacity of 150ml indicated by the volume graduation printed on the collection chamber.

DISPOSAL

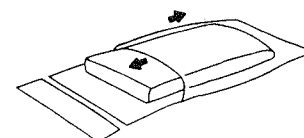
The PLEUR-EVAC Unit should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.

TO OPEN PACKAGE

1. Grasp the bottom edge of flap and pull up toward sterile opening.



2. Pull flap back pushing the wrapped unit out of bag, OR... Completely remove the breather strip. Push the wrapped unit out of the bag using aseptic technique.



SET UP INSTRUCTIONS

If suction is prescribed, follow steps 1 through 5. If suction is not required, follow steps 1 and 2 only.

1. FILL WATER SEAL CHAMBER WITH STERILE WATER OR SALINE

Fill the Water Seal Chamber to the "FILL LINE" on the Water Seal Pressure Scale to establish the one-way seal for patient protection. This is the 2 cm water level which will require approximately 70 ml (Figure 1).

A funnel is provided to facilitate filling. Attach the funnel to the connector on the suction tube.

Hold the funnel so that it is below the level of the top of the PLEUR-EVAC Unit and the suction tube is crimped. Fill the funnel with sterile water or saline to the fill line on the funnel.

Raise the funnel above the PLEUR-EVAC Unit and release the crimp in the tube. Water will enter and fill the Water Seal Chamber to the fill line. Once filled, the water seal will turn blue.

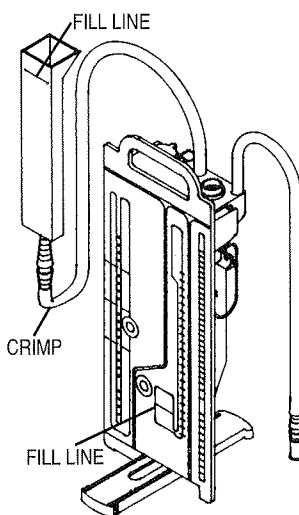


FIGURE 1

2. CONNECT TO THE PATIENT THORACIC CATHETER

Connect the patient tube, which is the long tube from the Collection Chamber, to the patient's thoracic catheter (Figure 2).

A connector is provided at the end of the patient tube for easy connection to the thoracic catheter. This connector is capped to maintain aseptic technique during set-up. DISCARD cap on patient tube after removing.

3. CONNECT TO SUCTION SOURCE

Connect the suction tube to the suction source (Figure 2).

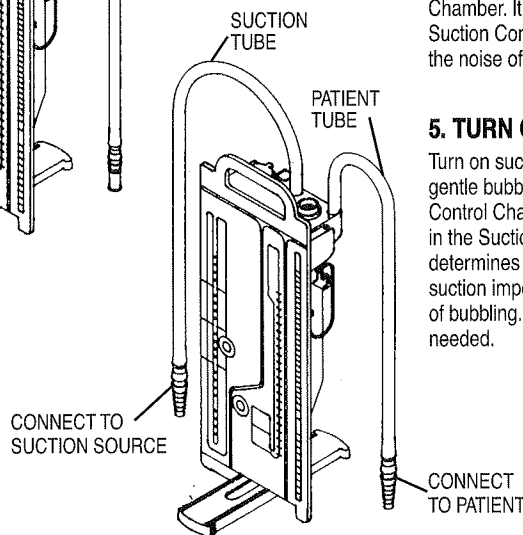


FIGURE 2

4. FILL SUCTION CONTROL CHAMBER WITH STERILE WATER OR SALINE

Remove the atmospheric vent cover (muffler) and fill through atmospheric vent to the 20 cm level or as prescribed. Once filled, water in the Suction Control Chamber will turn blue. Replace muffler after filling. The muffler, when in place, allows air to enter the Suction Control Chamber. It reduces evaporation in the Suction Control Chamber and dampens the noise of bubbling.

5. TURN ON SUCTION

Turn on suction and increase suction until gentle bubbling appears in the Suction Control Chamber. The height of the water in the Suction Control Chamber determines the approximate amount of suction imposed **regardless** of the degree of bubbling. Gentle bubbling is all that is needed.

PLEUR-EVAC® CHEST DRAINAGE INSTRUCTIONS

A. SUCTION CONTROL CHAMBER

S-1 ATMOSPHERIC VENT

Use the Atmospheric Vent opening for filling the Suction Control Chamber. This is also the vent to atmosphere. Do not cover this vent with anything other than the atmospheric vent cover (muffler). The muffler allows air to enter the Suction Control Chamber. The muffler also reduces evaporation in the Suction Control Chamber and dampens the noise of the bubbling.

S-2 SELF-SEALING DIAPHRAGM

A Self-Sealing Diaphragm is provided on the face of the PLEUR-EVAC Unit. Use an 18 gauge (1,24 mm) or smaller needle, attached to a syringe, to remove fluid from the Suction Control Chamber.

S-3 SUCTION CONTROL PRESSURE SCALE

When suction is applied and bubbling occurs, the approximate level of suction imposed is determined by the original fluid level.

NOTE: Evaporation may cause a decrease in the fluid level. Monitor fluid level periodically by momentarily discontinuing suction and observing the fluid level in the calibrated Suction Control Pressure Scale. If needed, fluid may be added through the Atmospheric Vent or the Self-Sealing Diaphragm (while suction is discontinued) to prescribed level. Be sure to resume suction.

In the presence of a large patient air leak, air flow through the PLEUR-EVAC Unit may be increased by increasing source suction. This will NOT increase suction imposed on the patient.

Check the unit periodically to ensure that adequate suction is being applied to the unit and that gentle bubbling is present in the Suction Control Chamber.

NOTE: To avoid spillover of water from the Suction Control Chamber into the Water Seal Chamber, gentle and controlled bubbling in the Suction Control Chamber is recommended.

S-4 SUCTION TUBE for connection to suction source, if suction is prescribed.

GRAVITY DRAINAGE—If gravity drainage is prescribed, the suction tube should remain **UNCAPPED** and free of **OBSTRUCTIONS**, to allow air to exit and minimize possibility of tension pneumothorax.

B. WATER SEAL CHAMBER

The Water Seal Chamber 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:

1. Check that all connections are secure and air tight.
2. If there is no external air leak, air is coming from the pleural space.

W-1 WATER SEAL PRESSURE SCALE

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 calibrated Water Seal Pressure Scale.

WITH SUCTION, add the reading from the Suction Control Chamber setting to the reading of the Water Seal Pressure Scale. (Example: -20 suction plus -10 water seal = -30 cm H₂O patient negativity.)

PATENCY of the patient's thoracic catheter can be observed as oscillation in the Water Seal Chamber. The water level rises and falls as the patient breathes. 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.

W-2 POSITIVE PRESSURE RELIEF VALVE

opens with increases in positive pressure, preventing pressure accumulation.

WARNING: Do not obstruct the Positive Pressure Relief Valve.

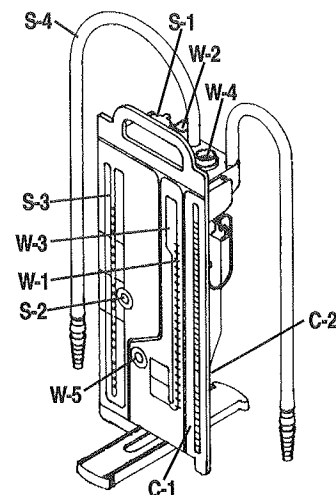
W-3 HIGH NEGATIVITY FLOAT VALVE preserves the water seal in the presence of high negativity. Water floats the valve up into the closed position when excessive negativity occurs. The valve opens upon a decrease in the negativity. The High Negativity Relief Valve (**W-4**) may be used to reduce negativity.

W-4 FILTERED HIGH NEGATIVITY RELIEF VALVE is provided to vent excessive negativity. Depress the button to relieve negativity. Filtered 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 pressure scale, has been attained.

WARNING: Stripping or milking of the patient drainage tube can cause excessive negativity. Use the High Negativity Relief Valve to restore negativity to prescribed levels.

CAUTION: If suction is not operative, or if operating on gravity drainage, depressing the High Negativity Relief Valve can reduce negative pressure within the Collection Chamber to zero (atmosphere) with the resulting possibility of a pneumothorax.

W-5 SELF-SEALING DIAPHRAGM is provided in the front of the unit to adjust the fluid level in the Water Seal Chamber. Sterile water or saline may need to be added due to evaporation. Fluid may need to be withdrawn if the chamber is overfilled. To adjust water seal level, use a syringe with an 18 gauge (1,24 mm) or smaller needle. Angle the needle downward to withdraw fluid.



C. COLLECTION CHAMBER

C-1 COLLECTION CHAMBER has a capacity of 150 ml ($\pm 10\%$). The Collection Chamber is calibrated in 0,5 ml increments up to 10 ml and 1 ml increments up to 150 ml.

When drainage reaches 150 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 and following the set-up and operating instructions.

CAUTION: Monitor the PLEUR-EVAC collection chamber. To avoid overflow, replace the unit before exceeding the fill capacity of 150ml indicated by the volume graduation printed on the collection chamber.

C-2 SAMPLING PORT

A self-sealing diaphragm is provided in the back of the Collection Chamber for taking samples of patient drainage. Use an 18 gauge (1,24 mm) or smaller needle, attached to a syringe, for withdrawing samples.

D. OTHER FEATURES

An attached telescoping floorstand swings out to stabilize the PLEUR-EVAC Unit when it is set on the floor. The floorstand contains an automatic locking mechanism that locks the floorstand in the open position. Grasp and pull the front and back edges of the floorstand to fully extend the floorstand for maximum stability. To close, press the locking tab and rotate the floorstand.

A carrying handle is provided for ease of patient ambulation or transport of the unit.

Marking surfaces are for making notations. Use pen or pencil.

Two hangers are provided to hang the PLEUR-EVAC Unit from a bed, O.R. stand or stretcher.