



DRY CONTROL CHEST DRAINS

Instructions For Use

Description

The Atrium Express™ Dry Control Chest Drain is a drainage device that incorporates a 2 liter collection chamber, suction control regulator, vacuum protection valve, and air leak monitor. The Express™ drain does not require the addition of water to operate. Sterile water or saline is required only for air leak detection. The drain is provided as a sterile, non-pyrogenic unit intended for single patient use. For models equipped with an in-line connector, use of an Atrium in-line ATS (Autotransfusion System) bag will provide a method for postoperative ATS collection. ATS chamber models have an access line for conducting continuous autotransfusion with an infusion pump, or for use with an Atrium self-filling ATS blood bag.

Indications For Use

- To evacuate air and/or fluid from the chest cavity or mediastinum.
- To help re-establish lung expansion and restore breathing dynamics.
- To facilitate collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in post-operative and trauma blood loss management.

Warnings

1. Do not obstruct the positive pressure valve located on top of drain.
2. Do not use manual high negativity vent to lower water seal column when suction is not operating or when patient is on gravity drainage.
3. For models equipped with in-line connector, do not separate connector prior to clamping off patient tube.
4. For models equipped with patient tube clamp, do not keep closed during drainage collection or patient transit.
5. Do not puncture patient tube with an 18 gauge or larger needle.
6. Do not open or remove disposal port during patient use.

Precautions

1. Federal (U.S.A) law restricts this device to sale by or on the order of a physician. Only persons trained in thoracic cavity drainage techniques should use this system.
2. Do not overfill the air leak monitor above the fill range.
3. Suction source should be set to -80mmHg or higher for regulator settings of -20cmH₂O or greater.
4. Chest drain must be kept below the patient's chest.
5. For total system disconnection, clamp off all indwelling thoracic catheters prior to disconnecting patient tube from patient.
6. This product is a single patient use device and should not be resterilized.
7. Replace chest drain if damaged.
8. Replace chest drain when collection volume exceeds maximum capacity.

Set Up

For models equipped with an in-line connector, move the patient tube clamp next to the in-line connector for set up convenience and patient safety. For air leak diagnostics a maximum of 30ml of water or saline will be required. Follow hospital's protocol for type of water to be used. Follow steps 1-4 and refer to additional details concerning system set up and operation.

Step 1. Connect Chest Drain To Patient - Remove patient tube connector cap and insert stepped patient tube connector into patient catheter. Connect chest drain to patient prior to initiating suction. Once drain is connected, a one-way seal to the patient is established via the vacuum protection valve.

Step 2. Connect Chest Drain To Suction - To apply suction, connect suction source vacuum line directly to chest drain suction line stepped connector. The suction control regulator is preset to -20cmH₂O.

Step 3. Turn Suction Source On - Increase suction source vacuum to -80mmHg or higher. The suction monitor bellows must be expanded to the ▲ mark or beyond for a -20cmH₂O or higher regulator setting. Expansion of the bellows across the suction monitor window will confirm suction operation. The suction control regulator dial, located on the side of the drain, can be adjusted to any suction setting between -10cm and -40cmH₂O.

Step 4. Optional Air Leak Detection - To observe patient air leaks, fill the air leak monitor with 30ml of sterile saline to the fill line via the needleless injection port located on the front of the drain. Once filled, water becomes tinted blue.

Suction Line Connector Port

During patient transit or when suction is not operating, it is not required to cap off the suction line connector port.

Suction Source

The suction source should provide a minimum vacuum pressure of -80mmHg at 20 liters of air flow per minute for a suction control setting of -20cmH₂O or greater. The suction source vacuum should be greater than -80mmHg when multiple chest drains are connected to a single suction source.

Suction Monitor Bellows

When the suction control regulator is set at -20cmH₂O or higher, the bellows must be expanded to the ▲ mark or beyond when suction is operating. If the bellows is observed to be expanded, but less than the ▲ mark, the suction source vacuum pressure must be increased to -80mmHg or higher. For a regulator setting less than -20cmH₂O suction (-10cmH₂O), any observed bellows expansion across the monitor window will confirm suction operation. The bellows need not be expanded to the ▲ mark for suction pressures less than -20cmH₂O, just visibly expanded to confirm suction operation.

Continually Adjustable Dry Suction Control

Suction pressure is preset to a -20cmH₂O level directly out of the package. Suction pressure can be reset to any desired pressure level between -10cmH₂O and up to a maximum of -40cmH₂O. Changing the suction control setting is easily accomplished by adjusting the rotary suction control dial located on the side of the drain. Dial down to lower the suction setting and dial up to increase the suction pressure setting.

NOTE: When changing suction pressure from a higher to a lower level, use of the manual high negativity vent after regulator adjustment will reduce excess vacuum down to the lower prescribed level.

Gravity Drainage

For gravity drainage applications, the drain must be placed below the patient's chest in an upright position. Disconnect the suction source vacuum line from the suction line connector port.

Placement Of Unit

Always place chest drain below the patient's chest in an upright position. To avoid accidental knockover, place the unit on the floor or hang it bedside with the hangers provided.

Positive Pressure Valve

Atrium's positive pressure valve, located on top of drain, opens instantly to release accumulated positive pressure. Do not obstruct the positive pressure valve.

Recording Drainage Volume

1. Single Collection Model

The first collection section is calibrated in 1ml increments up to 100ml. Subsequent collection sections are calibrated in 10ml increments up to 1200ml and 10ml increments up to a maximum capacity of 2100ml.

2. ATS Chamber Model

The ATS chamber is calibrated in 10ml increments up to 1200ml. The subsequent non-ATS collection section is also calibrated in 10ml increments up to a maximum capacity of 2100ml.

Verifying Suction Operation Via The Suction Monitor Bellows

The bellows located in the suction monitor will expand only when suction is operating. The monitor bellows will not expand when suction is not operating or disconnected. The calibrated ▲ mark allows quick and easy confirmation of vacuum operation over a wide range of continuously adjustable suction control settings.

Increase Vacuum Source When Bellows Is Not Expanded To The ▲ Mark

If the bellows is observed to be expanded, but less than the ▲ mark, the vacuum source pressure must be increased to -80mmHg or higher.

Observing Air Leak Monitor For Patient Air Leaks

If patient air leak detection is required, the air leak monitor must be filled with sterile water or saline to the fill line via the needleless injection port located on the front face of the drain. When air bubbles are observed in the blue tint water going from right to left, this will confirm a patient air leak. Continuous bubbling in the bottom of the air leak monitor will confirm a persistent air leak. Intermittent bubbling in the air leak monitor will confirm the presence of an intermittent air leak. No bubbling will indicate no air leak is present.

For Models Equipped With A Graduated Air Leak Monitor

Air leaks can range from 1 (low) to 5 (high). Air bubbles create an easy-to-follow air leak pattern for monitoring patient air leak trends.

Vacuum Indicator

When vacuum is present in the collection chamber, a 3symbol will remain visible in the vacuum indicator window. When vacuum is not present (atmospheric pressure) no symbol will appear. All patient tube connections and the vacuum indicator window should be checked regularly for vacuum confirmation.

Manual High Negativity Vent

To manually lower the height of the air leak monitor column or to lower patient pressure when connected to suction, temporarily depress the filtered manual vent located on top of the drain until the water column returns to the desired level. Do not use manual vent to lower air leak monitor column when suction is not operating or when the patient is on gravity drainage.

Automatic High Negativity Relief

The Express™ incorporates an advanced automatic high negativity relief valve. This filtered valve activates automatically to limit system pressure to approximately -65cmH₂O.

For Models Equipped With In-Line Patient Tube Connector

The locking in-line patient tube connector provide convenient system replacement, simple disconnection after use, and rapid in-line ATS blood bag attachment when required. The in-line connector must remain securely connected at all times during operation and patient connection. Clamp off patient tube clamp before separating in-line connector.

Patient Tube Clamp

The patient tube clamp provided with in-line connector models must remain open at all times during system operation. It is recommended to move the patient tube clamp next to the in-line connector (closer to chest drain) for set up convenience and routine visual check. Do not keep patient tube clamp closed when system is connected to patient. Patient tube clamp must be closed prior to in-line connector separation.

Sampling Patient Drainage

Sampling patient drainage must be in accordance with approved hospital infection control standards. Fluid samples can be taken directly from the needleless access port located on the in-line connector or from the patient tube by forming a temporary dependent loop and inserting a 20 gauge needle at an oblique angle. Do not puncture patient tube with an 18 gauge or larger needle.

System Disconnection

For models equipped with an in-line connector, close patient tube clamp prior to disconnecting chest drain patient tube from patient. For maximum protection, clamp off all indwelling thoracic catheters prior to disconnecting the chest drain patient tube from the patient's catheter.

For Models Equipped With A Disposal Port

The disposal port should be opened for pouring out collected contents or adding decontamination / solidifying agents after patient use. Do not open disposal port during patient use. It is recommended that all necessary infection control precautions be taken while handling and disposing of collected contents, including the use of hospital approved personal protective equipment.

System Disposal

Handling and disposal of a discarded chest drain and its contents should be in accordance with all applicable regulations including, without limitation, those pertaining to the safety of human health and the environment.

SYMBOLS USED ON PRODUCT LABELS

 CODE NUMBER

 LOT NUMBER

 STERILE. STERILIZED BY GAMMA RADIATION.

 SEE PACKAGE INSERT

 SINGLE USE ONLY

 EXPIRATION DATE



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