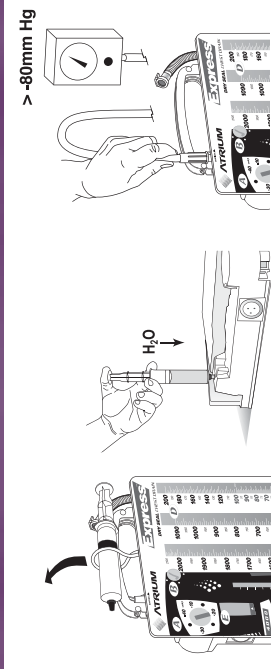


Instructions For Use

Set Up

- Step 1. Connect Patient Tube To Patient –**
Connect chest drain to patient prior to initiating suction.
- Step 2. Connect Suction To Chest Drain –**
Attach suction line to suction port on top of chest drain.
- Step 3. Turn Suction Source On –** Increase suction source vacuum to -80mmHg or higher. Suction regulator is preset to -20cmH₂O. Adjust as required.
- Step 4. Fill Air Leak Monitor **C** to Fill Line –**
Fill air leak monitor to the fill line by syringe (no needle) with 30ml of sterile water or sterile saline via the needleless injection port located on the back of the drain. For models available with sterile fluid, twist top off syringe and insert tip into needleless luer port. Depress syringe plunger into luer port and squeeze contents into air leak monitor until fluid reaches fill line.



USA

GB

Dry Seal Chest Drain

F

D

E

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P

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GR

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Système de drainage thoracique étanche
 Thoraxdrainagegerät für trockene Saugung
 Drenaje torácico con sellado en seco
 Drenaggio toracico con tenuta a secco
 Drenagem torácica com selo a seco
 Thoraxdrain met droge verzegeling
 Θωρακική παροχέτευση με στεγνή στεγανότητα
 乾式密閉胸部ドレーン

ATRIUM

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 Rev. 2011/07

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www.atriummed.com

www.atriummed.com/ExpressIFU

Description

The Atrium Express™ chest drain is a disposable, waterless operating system with 2100ml collection volume, dry suction regulator, dry one-way valve for seal protection, and air leak monitor with redundant water seal protection. Water is not required for seal protection or drain operation. However, sterile fluid (provided with selected models) is required for air leak detection and water seal function. The Express drain is packaged sterile, or is packaged in a sterile fluid path format (only the contents of the sterile patient tube pack can be entered into the sterile field). This chest drain is non-pyrogenic and is for single patient use only. Models equipped with a patient tube in-line connector provide convenient system change out or attachment of an Atrium in-line ATS Bag for postoperative autotransfusion. Express ATS models include a filtered collection chamber with an access line for continuous autotransfusion with an infusion pump, or for use with an Atrium self-filling ATS blood bag.

Indications For Use

- Evacuate air and/or fluid from the chest cavity or mediastinum.
- Help re-establish lung expansion and restore breathing dynamics.
- Facilitate postoperative collection and reinfusion of autologous blood from the patient's pleural cavity or mediastinal area.

Warnings

1. Do not obstruct the positive pressure relief valve located on top of drain.
2. Do not manually depress high negativity vent when patient is on gravity drainage or when suction is not operating.
3. Do not separate patient tube in-line connector prior to clamping off patient tube first.
4. Do not keep patient tube clamp closed during drainage collection or patient transport.
5. Do not puncture patient tube with an 18 gauge or larger needle.
6. Do not use or puncture needleless luer port with needle.
7. For single patient use only. Do not reuse, reprocess or resterilize. 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.

Precautions

1. For sterile fluid path models, only the contents of the sterile patient tube pack should be entered into the sterile field.
2. Do not overfill the air leak monitor above the fill line.
3. Suction source should be set to -80mmHg or higher for chest drain regulator settings of -20cmH₂O or greater.
4. Express chest drain must be kept below the patient's chest in an upright position.
5. Replace chest drain if damaged or when collection volume meets or exceeds maximum capacity.
6. Patient tube connections, air leak monitor, vacuum indicator, suction regulator and bellows should be checked regularly to confirm proper operation.
7. Pre-packaged sterile fluid for chest drainage use only.

Set Up

- Step 1. Connect Patient Tube To Patient** – Connect chest drain to patient prior to initiating suction.
- Step 2. Connect Suction To Chest Drain** – Attach suction line to suction port on top of chest drain.
- Step 3. Turn Suction Source On** – Increase suction source vacuum to -80mmHg or higher. Suction regulator is preset to -20cmH₂O. Adjust as required.
- Step 4. Air Leak Monitor** – Fill air leak monitor to fill line by syringe (no needle) with 30ml of sterile water or sterile saline via the needleless injection port located on the back of the drain. For models available with sterile fluid, twist top off syringe and insert tip into needleless luer port. Depress and hold tip of syringe against luer port and squeeze contents into air leak monitor until fluid reaches fill line.

Set Up For Sterile Fluid Path Models

- Step 1. Connect Patient Tube To Patient** – Open sterile patient tube pack and pass only the sterile patient tube into sterile field. Close patient tube clamp prior to connecting patient tube to catheter.
- Step 2. Connect Patient Tube To Chest Drain** – Pass distal end of patient tube out of sterile field for connection to chest drain. Connect patient tube to chest drain prior to initiating suction.
- Step 3. Connect Suction To Chest Drain** – Attach suction line to suction port on top of chest drain.
- Step 4. Turn Suction Source On** – Increase suction source vacuum to -80mmHg or higher. Suction regulator is preset to -20cmH₂O. Adjust as required.
- Step 5. Air Leak Monitor** – Fill air leak monitor to the fill line by syringe (no needle) with 30ml of sterile water or sterile saline via the needleless injection port located on the back of the drain. For models available with sterile fluid, twist top off syringe and insert tip into needleless luer port. Depress and hold tip of syringe against luer port and squeeze contents into air leak monitor until fluid reaches fill line.

Placement of Unit

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

Gravity Drainage

Disconnect the suction line and maintain drain below the patient's chest in an upright position.

Suction Port

Suction port is located on top of the drain. It is not required to cap off suction port when suction is not connected or operating.

Suction Source

Suction source should provide a minimum vacuum pressure of -80mmHg at 20 liters of airflow per minute for a suction control setting of -20cmH₂O or greater.

Suction Bellows

Suction bellows will expand to the ▲ mark or beyond when suction is connected and operating at a regulator setting of -20cmH₂O or higher. If the bellows is expanded but less than the ▲ mark, **increase the suction source vacuum to -80mmHg or higher.** For regulator settings less than -20cmH₂O, any visible bellows expansion in bellows window will confirm suction operation.

Dry Suction Regulator

Suction regulator is preset to -20cmH₂O and can be adjusted from -10cmH₂O to -40cmH₂O. To change suction setting adjust rotary suction regulator dial located on the side of the drain. Dial **down to lower** suction pressure and dial **up to increase** suction pressure. To lower regulator setting from a higher level (-40cmH₂O) to a lower level (-20cmH₂O), adjust regulator down to lower setting and then temporarily depress the manual high negativity vent located on top of the drain to reduce excess vacuum.

Dry One-Way Seal Valve

Atrium's dry seal valve technology does not require water for seal protection during patient use. Every Express chest drain and seal valve is 100% leak tested prior to shipment. Atrium's dry seal protection system is not position sensitive for maximum safety and convenience during patient transport.

Vacuum Indicator

✓ mark symbol will remain visible in the **vacuum indicator** window when vacuum is present inside the drain. When no vacuum is present inside drain, no ✓ mark symbol will appear (unit is at atmospheric pressure).

Air Leak Monitor

The graduated air leak monitor with redundant water seal protection must be filled for air leak detection and operation. Once filled, fluid becomes tinted blue. When air bubbles are observed going from right to left, this will confirm an air leak. Air leak bubbling can range from 1 (low) to 5 (high). Air bubbles create an easy to follow air leak pattern for monitoring patient air leak trends.

Collection Chamber

The Express 4000 Adult • Pediatric Model:

The first collection column is calibrated in 1ml increments up to 100ml and 2ml increments up to 200ml. Column two is calibrated in 10ml increments up to 1090ml. Column three is calibrated in 10ml increments up to 2100ml.

The Express 4020 Dual Collection Model:

Column 1 is calibrated in 1 ml increments up to 100ml and 2ml increments up to 200ml. Subsequent drainage is calibrated in 10ml increments up to 1090ml. Column 2 is calibrated in 10ml increments up to 900ml.

The Express 4012 Baby Drain Model:

The pediatric collection column is calibrated in 1ml increments up to 100ml and 2ml increments up to 200ml.

The Express 4050 ATS Model:

The first collection column is calibrated in 10ml increments up to 1100ml. Column two is calibrated in 10ml increments from 1110ml up to 2100ml.

Fluid level graduations are accurate within ± 3ml or 3% of scale.

Automatic High Negativity Release Valve

The high negativity release valve automatically activates when required to limit maximum vacuum pressure to approximately -50cmH₂O.

Manual High Negativity Vent

To lower chest drain vacuum pressure when connected to suction, temporarily depress the high negativity vent located on top of the drain.

Positive Pressure Relief Valve

PPRV located on top of drain opens instantly to release positive pressure.

Advanced Knock-over Protection

The Express incorporates special internal knockover protection baffles. In the event of collection chamber fluid spills, simply hold unit upright and gently tip unit to one side to adjust collection chamber fluid levels.

Sampling Drainage

Must be in accordance with approved hospital infection control standards. Selected models include a needleless luer port on the patient tube connector for sampling patient drainage. Alcohol swab luer port prior to syringe attachment (no needle). Samples can also be taken directly from the patient tube by inserting a 20 gauge needle or smaller with syringe. Alcohol swab patient tube prior to inserting syringe needle at a shallow angle.

System Disconnection

Clamp off patient tube or all indwelling thoracic catheters prior to disconnecting chest drain from patient.

System Disposal

Disposal of chest drain and its contents should be in accordance with all applicable regulations.

SYMBOLS USED ON PRODUCT LABELS

REF CODE NUMBER **LOT** LOT NUMBER

STERILE **EO** STERILE. STERILIZED BY ETHYLENE OXIDE.

SEE PACKAGE INSERT SINGLE USE ONLY EXPIRATION DATE

ATS BAG COMPATIBLE ATS CHAMBER

S F P STERILE FLUID PATH PACKAGE **Rx Only** PRESCRIPTION ONLY

LF LATEX FREE

Latex Free

This device is covered under one or more of the following U.S. patents: 4,988,342; 5,114,416; 5,141,504; 5,154,712; 5,380,314; 5,397,299; 5,401,262; 5,807,358; 6,210,383 B1
Other patents pending.
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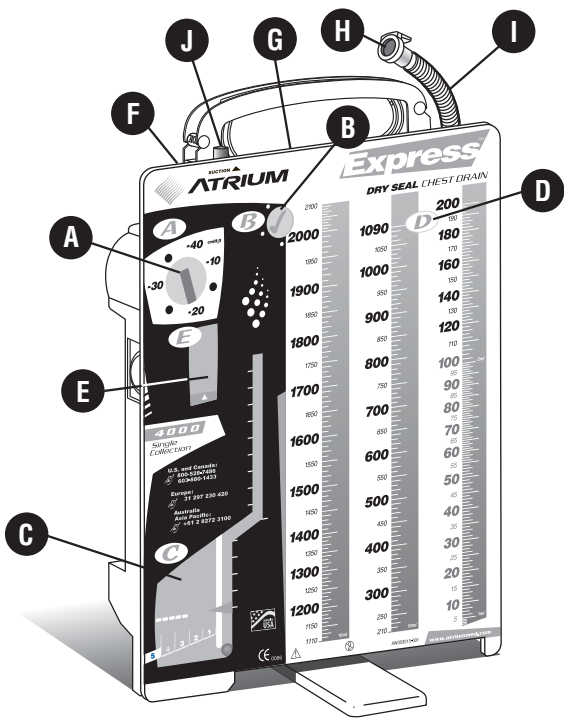
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Express™

DRY SEAL CHEST DRAIN



USA

GB Features:

- A** Suction Control Regulator
- B** Vacuum Indicator
- C** Air Leak Monitor
- D** Collection Chamber
- E** Suction Monitor Bellows
- F** Positive Pressure Release Valve
- G** Manual High Negativity Vent
- H** In-Line Connector
- I** Patient Tube
- J** Suction Port

F Comprend:

- A** Régulateur de contrôle de l'aspiration
- B** Indicateur de vide
- C** Détecteur de fuites d'air
- D** Chambre de collecte
- E** Accordéon témoin de l'aspiration
- F** Soupape de haute pression positive
- G** Valve manuelle de haute pression négative
- H** Connecteur en ligne
- I** Tubulure patient
- J** Orifice d'aspiration

D Merkmale:

- A** Sogkontrollregler
- B** Vakuumanzeige
- C** Luftleckmonitor
- D** Sammelkammer
- E** Blasebalg des Saugmonitors
- F** Überdruckventil
- G** Manuelle Hochnegativitäts-Belüftung
- H** In-Line-Schlauchverbinder
- I** Patientenschlauch
- J** Sauganschluss

E Características:

- A** Regulador para el control de aspiración
- B** Indicador de vacío
- C** Monitor de fugas de aire
- D** Cámara de recolección
- E** Fuelle del regulador de aspiración
- F** Válvula de liberación de presión positiva
- G** Válvula manual de alta negatividad
- H** Conector en línea
- I** Tubo del paciente
- J** Orificio de aspiración

I Caratteristiche:

- A** Regolatore dell'aspirazione
- B** Indicatore del vuoto
- C** Monitor delle perdite d'aria
- D** Camera di raccolta
- E** Soffietto del monitor dell'aspirazione
- F** Valvola di sfogo della pressione positiva
- G** Sfiato manuale per l'alta negatività
- H** Connettore in linea
- I** Tubo del paziente
- J** Apertura di aspirazione

P Características:

- A** Regulador Para Controlo de Aspiração
- B** Indicador de Vácuo
- C** Monitor de Fugas de Ar
- D** Câmara de Drenagem
- E** Harmónio do Monitor de Aspiração
- F** Válvula de Escape de Pressão Positiva
- G** Válvula Manual para Alta Negatividade
- H** Engate em linha
- I** Tubo do Paciente
- J** Porta de aspiração

NL Onderdelen:

- A** Zuigkrachtregelaar
- B** Vacuümindicator
- C** Luchtlekmonitor
- D** Opvangreservoir
- E** Balg zuigkrachtmonitor
- F** Overdrukklep
- G** Handmatig bediende beluchting hoge negatieve drukontlasting
- H** In-line connector
- I** Patiëntslang
- J** Afzuigpoort

GR Χαρακτηριστικά:

- A** Ρυθμιστής Ελέγχου Αναρρόφησης
- B** Δείκτης Κενού
- C** Μόνιτορ Διαρροής Αέρα
- D** Θάλαμος Συλλογής
- E** Φυσερό Μόνιτορ Αναρρόφησης
- F** Βαλβίδα Απελευθέρωσης Θετικής Πίεσης
- G** Χειροκίνητος Εξαερισμός Υψηλής Αρνητικότητας
- H** Ενσωματωμένο Βύσμα
- I** Σωλήνας Ασθενή
- J** Θύρα αναρρόφησης

J 特徴:

- A** 吸引制御調節器
- B** バキューム表示
- C** エアーリークモニター
- D** 回収チャンバー
- E** 吸引モニターベロー
- F** 陽性圧リリース弁
- G** 手動式高陰性ペント
- H** インラインコネクター
- I** 患者チューブ
- J** 吸引ポート



ATRIUM