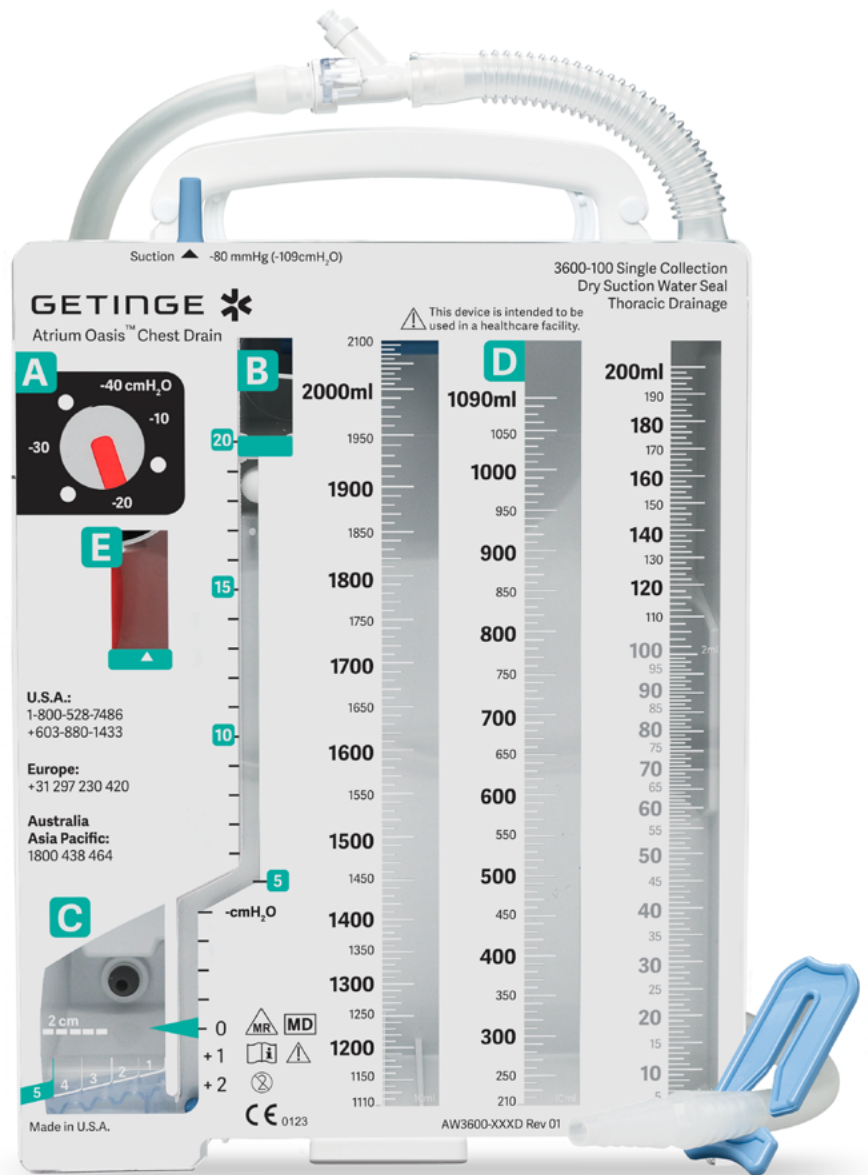




Instructions for use

Atrium Oasis Chest Drain Single Collection Dry Suction Water Seal

en Dry Suction Water Seal Chest Drain

Instructions for use

Description

The Atrium Oasis Chest Drain for thoracic drainage is a single collection, disposable, dry suction operating system with 2100 ml collection volume, dry suction regulator, graduated water seal, and graduated air leak monitor. Provided sterile fluid is required for water seal operation and air leak detection.

The drainage tubing in-line connector provides convenient system change out. The chest drain is packaged sterile and intended for single patient use only.

Expected Clinical Benefits

Use of the chest drain in the thoracic application allows re-establishment of the normal negative pleural pressure and facilitates restoration of physiologic breathing.

Use of the chest drain in the mediastinal application prevents the accumulation of fluid in the mediastinal space. This reduces the risk of morbidity, such as cardiac tamponade.

Indications For Use

- Evacuate air and/or fluid from the chest cavity or mediastinum
- Help re-establish lung expansion and restore breathing dynamics

Indications For Use (EU)*

The chest drain is indicated for use with adult patients for medical conditions in which evacuation of air and/or fluid (including blood) is required from the pleural cavity or mediastinum. These include pneumothorax, post-operative cardiac or thoracic surgery, thorax injury, pleural effusion, pleural empyema, and other related conditions requiring thoracic drainage.

Intended Users and Target Patient Population

The chest drain is intended to be used by trained healthcare professionals familiar with cardiothoracic surgical procedures and techniques, including the use of chest drains.

The chest drain is intended for use in adult patients. The safety and effectiveness of the chest drain has not been established in pregnant or lactating patients.

Intended Use (EU)*

The chest drain is intended to evacuate air and/or fluid (including blood) from the pleural cavity or mediastinum when thoracic drainage is required.

* Geographies that accept CE Mark product.

Contraindications

Not for use outside of the pleural cavity or mediastinum.

Warnings

⚠ Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

1. Do not obstruct the positive pressure release valve located on top of drain. Occlusion may cause tension pneumothorax or may compromise respiratory function.
2. Do not manually depress high negativity vent when patient is on gravity drainage or when suction is not operating. This

may open the pleural space to atmospheric pressure and compromise respiratory function.

3. Do not separate drainage tubing in-line connector prior to clamping off drainage tubing first. Doing so may result in opening the pleural space to atmospheric pressure and compromise respiratory function.
4. Do not keep drainage tubing clamp closed during drainage collection or patient intra-hospital transfer. Doing so will prevent drain operation and may compromise respiratory function if fluid drainage is stopped or an active pneumothorax is present.
5. Do not puncture drainage tubing with an 18 gauge (1.27 mm) or larger needle. The thermoplastic elastomer may not properly close the puncture. This may open the pleural space to atmospheric pressure and compromise respiratory function.
6. Do not use or puncture Luer Port with needle. Damage to the port with a loss of sealing may occur. This may open the pleural space to atmospheric pressure and compromise respiratory function.
7. Do not leave syringe or open Luer-lock connector attached to the Luer Port. Damage to the port with a loss of sealing may occur. Doing so may result in opening the pleural space to atmospheric pressure and compromise respiratory function.
8. 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.
9. Use of the chest drain is restricted for use by trained healthcare providers familiar with cardiothoracic surgical procedures and techniques, including the use of chest drains.

Precautions

1. Do not overfill water seal above the 2 cm fill line.
2. Suction source should be set to -80 mmHg (equivalent to -109 cmH₂O) or higher for chest drain regulator settings of -20 cmH₂O or greater.
3. Chest drain must be kept below the patient's chest in an upright position.
4. Replace chest drain if damaged or when collection volume meets or exceeds maximum capacity.
5. Drainage tubing connections, water seal, air leak monitor, suction regulator and bellows should be checked regularly to confirm proper operation.
6. Pre-packaged fluid for chest drain use only.
7. Do not use if device or package is damaged.
8. The chest drain is restricted for use in a healthcare facility. The chest drain should not be used for outpatient drainage.
9. Do not use if temperature and humidity (environmental limits) are exceeded.
10. Ensure proper setup of thoracic catheter(s) and drainage tubing connections to avoid potential kinking and/or tension at the thoracic catheter insertion site. For single collection chest drainage systems, one chest drain should be used per thoracic catheter.

Potential Adverse Effects/Residual Risks

Potential residual risks and undesirable side effects associated with the need and use for chest drainage, including foreseeable misuse, include allergic reaction, arrhythmia, bleeding, cardiac tamponade, cellulitis, empyema, fistula, infection, pain, pericardial effusion, pleural effusion, pneumothorax, prolonged air leak, seroma, and subcutaneous emphysema. Iatrogenic harm may occur from chest tube insertion, including tissue, organ, nerve or vessel damage. These harms may result in life-threatening complications or death. The patient should be advised to contact the physician should an adverse reaction occur. Any serious incident related to the device that occurs should be reported to the manufacturer and the appropriate regulatory authority in which the physician and/or patient is established. In the European Union the competent authority of the member state should also be notified.

Set Up

Step 1. Fill Water Seal To 2 cm Line – Add 45 ml of sterile water or sterile saline via the suction port located on top of the drain. Twist top off bottle and insert tip into suction port. Squeeze contents into water seal until fluid reaches 2 cm fill line.

Step 2. Connect Drainage Tubing To Compatible Catheter – Connect chest drain to catheter prior to initiating suction. Pre-attached stepped connector attaches to patient thoracic catheters size 24 – 40 Fr (8.0 – 13.3 mm).

Step 3. Connect Suction To Chest Drain – Attach suction line (not provided with device) to suction port on top of chest drain.

Step 4. Turn Suction Source On – Increase suction source vacuum to -80 mmHg (equivalent to -109 cmH₂O) or higher. Suction regulator is preset to -20 cmH₂O. Adjust as required. Suction bellows will expand to the ▲ mark or beyond when suction is connected and operating at a regulator setting of -20 cmH₂O or higher.

Water Seal

The water seal must be filled to the 2 cm fill line for system operation and air leak detection. Once filled, water seal becomes tinted blue. When air bubbles are observed going from right to left, this will confirm an air leak. The fluid level can be adjusted via the access port located on the back of the water seal chamber using a 19 gauge (1.07 mm) or smaller needle and syringe.

Placement of Unit

Always place the chest drain below the patient's chest in an upright position. To avoid accidental knock-over, place the unit on the floor using the floor stand or hang it bedside with the hangers. Rotate the floor stand at the base of the chest drain clockwise until completely swung out. Lift the hangers from inside the chest drain handle to hang bedside.

In the event of a knock-over immediately return the chest drain to an upright position and check the fluid level in the water seal chamber. Adjust the level of fluid using the access port on the back of the drain if needed. Ensure the floor stand is fully engaged.

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 -80 mmHg (equivalent to -109 cmH₂O) with ≥38 l/min free flow for a suction control setting of -20 cmH₂O or greater.

Suction Bellows

Suction bellows will expand to the ▲ mark or beyond when suction is connected and operating at a regulator setting of -20 cmH₂O or higher. If the bellows is expanded but less than the ▲ mark, **increase the suction source vacuum to -80 mmHg (equivalent to -109 cmH₂O) or higher.** For regulator settings less than -20 cmH₂O, any visible bellows expansion in bellows window will confirm suction operation.

Dry Suction Regulator

Suction regulator is preset to -20 cmH₂O and can be adjusted from -10 cmH₂O to -40 cmH₂O. 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 (-40 cmH₂O) to a lower level (-20 cmH₂O), 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.

Vacuum Potential

Maximum vacuum of -40 cmH₂O with a flow rate of ≥15 l/min.

Air Leak Monitor

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

Graduations

Column 1	1 ml increments up to 100 ml 2 ml increments up to 200 ml
Column 2	10 ml increments up to 1090 ml
Column 3	10 ml increments up to 2100 ml

Fluid level graduation accuracy ±10%
*For every 50 ml increment labeled between 0-2000 ml

Permanent ink can be used to write on the collection chamber for marking and tracking fluid collection.

Changes in Patient Pressure

With suction on, patient pressure will equal suction control setting **A** plus the height of water seal column level **B**. For gravity drainage (no suction) patient pressure will equal the height of the graduated water seal column level only.

Manual High Negativity Vent

To lower the height of the water seal column and to lower chest drain vacuum pressure when connected to suction, depress the high negativity vent located on top of the drain until the water seal column lowers to the desired level.

Positive Pressure Release Valve (PPRV)

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

Knock-over Protection

The chest drain incorporates special internal knock-over protection baffles that limit fluid redirection into and out of the water seal chamber.

Fluid Redirection

In the event of collection chamber fluid spills, simply hold the chest drain unit upright and gently tip to the right side, towards the drainage tubing, to adjust collection chamber fluid levels.

Sampling Drainage

Must be in accordance with approved hospital infection control standards. Patient drainage may be sampled from the Luer Port (1) or directly from the drainage tubing (2).

- 1 Alcohol swab the Luer Port prior to syringe attachment (no needle). Form a temporary loop and allow fluid to pool. See (1) on last page.
- 2 The drainage tubing is made of a thermoplastic elastomer that will close the puncture of a 20 gauge or smaller needle. Alcohol swab the drainage tubing prior to syringe insertion. Form a temporary loop and allow fluid to pool. Insert a 20 gauge (0.91 mm) needle at a shallow angle (<45°). See (2) on last page.

MRI Safety Information



The Atrium Oasis Chest Drain is MR Conditional. The chest drain unit must be kept outside of the MRI machine.

The drainage tubing and stepped connector are MR Safe. A patient with the drainage tubing and stepped connector can be safely scanned in an MRI machine of 3 Tesla or less.

Environmental Limits

Storage

Temperature: 15°C - 25°C (59°F - 77°F)
Relative Humidity: 0%RH – 80%RH

Transport

Temperature: 7°C - 45°C (44.6°F - 113°F)
Relative Humidity: 20%RH – 90%RH

System Disconnection

Clamp off drainage tubing 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.

Atrium Oasis Chest Drain Comapatible Accessories

(For sale in the U.S.A. only)

- Disposal Cap Part Number: 19910
- Pediatric Connector Part Number: 19915
- Step Down Connector Part Number: 19918

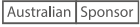
Symbols Used on Product Labels

 Catalogue number  Batch code  Medical device  Box quantity  Caution  Do not re-use

 Keep dry  Do not re-sterilize  Use-by date  Date of manufacture  Sterilized using ethylene oxide

 Manufacturer  Fragile, handle with care  Keep away from sunlight  Do not use if package is damaged

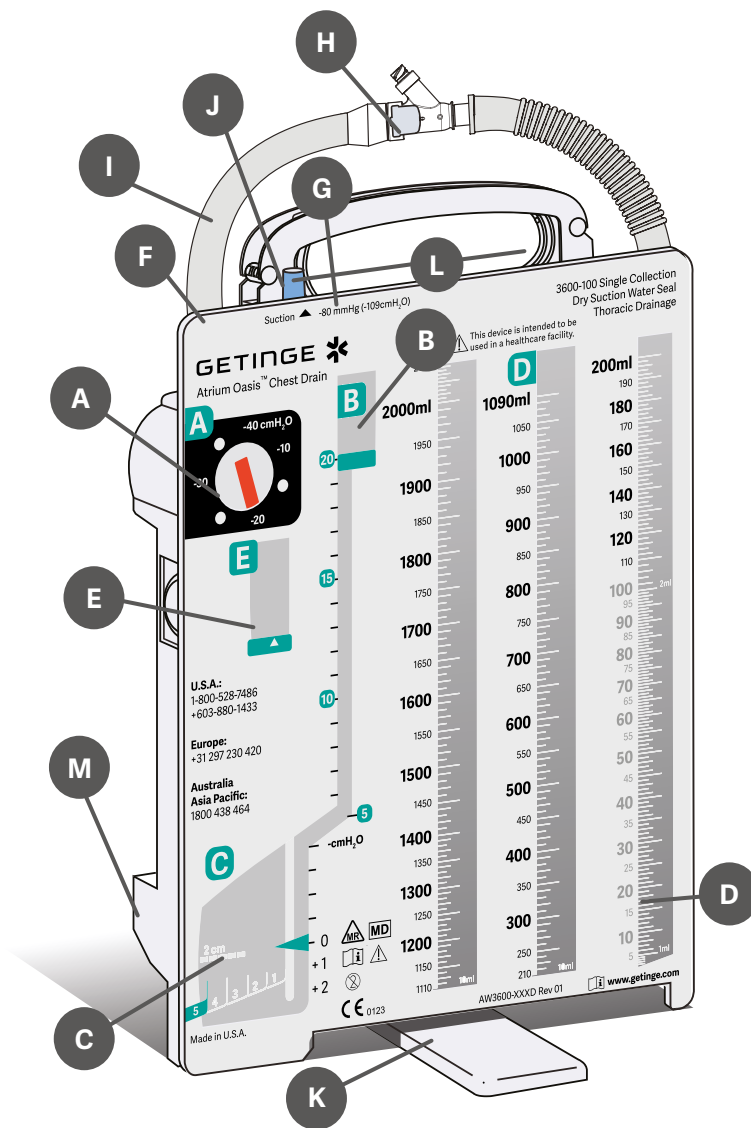
 Humidity limitation  Consult instruction for use  Temperature limit  Unique device identifier

 Australian Sponsor  Consult electronic instructions for use  MR Conditional

 Single sterile barrier system with protective packaging inside

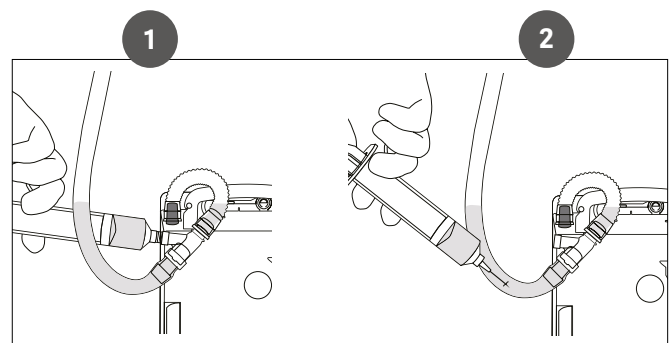
 Authorized representative in the European Community  Indicates the Swiss authorized representative

Rx Only  Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician



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- A** Suction Control Regulator
- B** Water Seal Column
- C** Water Seal/Air Leak Monitor
- D** Collection Chamber
- E** Suction Bellows
- F** Positive Pressure Release Valve
- G** Manual High Negativity Vent
- H** In-Line Connector with Luer Port
- I** Drainage Tubing
- J** Suction Port
- K** Floor Stand
- L** Hangers
- M** Access Port





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The Atrium Oasis Chest Drain is manufactured by Atrium Medical Corporation / 40 Continental Boulevard, Merrimack, NH 03054 / +1-603-880-1433

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