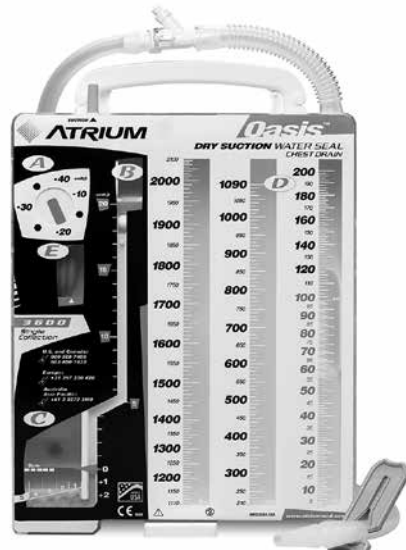


Oasis® Dry Suction Water Seal Chest Drain



Instructions For Use

www.maquet.com

en Dry Suction Water Seal Chest Drain

fr Système de drainage thoracique sec avec chambre de scelle au eau

de Thoraxdrainagegerät für trockene Saugung mit Wasserschlöss

es Dispositivo de drenaje torácico con cierre hidráulico de aspiración en seco

it Drenaggio toracico a tenuta d'acqua e aspirazione a secco

pl Dreno toracico de selo de água de aspiração a seco

nl Thoraxdrain met waterslot en droge zuigkracht

da Thoraxdræn med tørt sugning og vandforsøgning

sv Thoraxdränage med torr sugning och vattenlås

fi Kuiva vesitiivistetty pleuralämu

no Toraksdrenasje med tørr sugning og vannforsøgning

el Συσκευή Βασική για απορρόφηση με ξηρή απορρόφηση και στεγανοποίηση (σε ξηρό)

pl System do suchego drenażu suchego klatki piersiowej z zastawką wodną

zh 乾吸式密封胸引引流装置

ar أنبوب الصدر الجاف مع غرفة ختم المياه

cs Hrudní drenáž se suchým odsávním a s vodním uzávěrem

hu Száraz szívásos, víztömítéses mellkasdrén

ko 건조 흡입 수분 차단 배액

ru Грушевый дренаж для сухого всасывания с водяным затвором

tr Kuru Aspirasyon Su Sızdırmaz Güçlü Dreni

Instructions For Use

Description
The Oasis chest drain for thoracic drainage is a disposable, dry suction operating system with 2100 ml collection volume (200 ml for fibrinolytic drain), dry suction regulator, and graduated water seal. Selected models include a graduated air leak monitor. Sterile fluid provided with selected models is required for water seal operation and air leak detection. The Oasis drain is packaged sterile 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 for single patient use only.
The ATS chest drain models are non-primed, and single patient use only. Models equipped with patient tube in the connector provide convenient top-line change out or attachment of an in-line ATS bag for postoperative autotransfusion. Oasis ATS models include a filtered collection chamber with an access line for continuous suction/infusion with an infusion pump, or for use with a self-heating 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 reabsorption of subpleural or subcutaneous blood from the patient's pleural cavity or mediastinal area.

Contraindications

- See Contraindications in the Instructions for Use for the Thoracic Catheter or in the separate Autotransfusion Instructions for Use.

Warnings
Caution: Federal Law (BSA) restricts this device to sale by or on the order of a physician.

1. Do not occlude 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 negative 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 patient tube in the connector prior to clamping of patient tube first. Doing so may result in opening the pleural space to atmospheric pressure and compromise respiratory function.
4. Do not keep patient tube clamp closed during drainage collection or patient transport. Doing so will prevent drain operation and may compromise respiratory function if fluid drainage stopped or an active pneumothorax is present.
5. Do not puncture patient tube 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 needlessly. 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. Dual collector models (C patient tubes) require both patient tubes to remain connected to the patient. When using dual collection models with only one patient tube connection (1 tube only), the patient tube not in use must remain securely clamped off at all times.
8. For single patient use only. Do not reuse, reprimed or re-sterile. Reuse, repriming 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 can be entered into the sterile field.
 2. Do not exceed water seal above the 2 cm fill line.
 3. Suction source should be set to -80 mmHg or higher for chest drain regulator settings of -20 cmH₂O or greater.
 4. Chest drain must be kept below the patient's chest in an upright position.
 5. Replace chest drain if drainage or airway collection volume meets or exceeds maximum capacity.
 6. Patient tube connections, water seal, suction regulator and bellows should be checked regularly to confirm proper operation.
 7. The packaged sterile fluid for chest drainage use only.
 8. Do not use if device or package is damaged.
 9. Users should be familiar with thoracic surgical procedures and techniques before using a chest drain.

- 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. For models available with sterile fluid, seal top of tube and insert into suction port. Squirted contents into water seal until fluid reaches 2 cm fill line.
- Step 2. Connect Patient Tube To Patient** – Connect chest drain to patient 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 -80 mmHg 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.

Set Up for Sterile Fluid Path Models

- Step 1. Connect Patient Tube To Patient** – Open sterile patient tube and space only the sterile patient tube into sterile field. Close patient tube clamp prior to connecting patient tube to catheter.
- Step 2. Fill Water Seal To 2 cm Fill Line** – Add 45 ml of sterile water or sterile saline via the suction port located on top of the drain. For models available with sterile fluid, seal top of bottle and insert into suction port. Squirted contents into water seal until fluid reaches 2 cm fill line.
- Step 3. Connect Patient Tube To Chest Drain** – Press closed end of patient tube out of sterile field for connection to chest drain. Connect patient tube to chest drain prior to initiating suction. Open the patient tube clamp.
- Step 4. Connect Suction To Chest Drain** – Attach suction line to suction port on top of chest drain.
- Step 5. Turn Suction Source On** – Increase suction source vacuum to -80 mmHg 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.

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 on a gurney with the handles up.

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 of -80 mmHg with >38 l/min flow rate 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 or higher for regulator settings of -20 cmH₂O or higher. If any visible bellows expansion or bellows and/or seal 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 settings 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 negative vent located on top of the drain to reduce access vacuum.

Vacuum Potential
Maximum vacuum of -40 cmH₂O with maximum flow rate of 2-15 l/min.

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 inverted tube. When air bubbles are observed going from right to left, this will confirm an air leak. The fluid level can be adjusted as the access government located on the back of the water seal chamber using a 1/8" gauge (1.27 mm) or smaller needle and syringe.

Air Leak Monitor
Air leak bubbling can range from 1 drop to 5 (high). Air bubbles create an easy to follow air leak pattern for monitoring patient air leak trends.

Collection Chamber
The Oasis 3600 Single Collection Model:
The attached connector attaches to patient thoracic catheters size 24-40Fr.
The first collection column is graduated in 1 ml increments up to 100 ml and 2 ml increments up to 2100 ml.
Column two is graduated in 10 ml increments up to 100 ml.

The Oasis 3620 Dual Collection Model:
The attached connectors attach to patient thoracic catheters size 24-40Fr.
Column one (major collection, while patient tube clamp) is graduated in 1 ml increments up to 100 ml and 2 ml increments up to 200 ml.
Subsequent drainage is graduated in 10 ml increments up to 1000 ml.
Column two (minor collection, while patient tube seal) is graduated in 10 ml increments up to 1000 ml.

The Oasis 3612 Intra-Pleural Drain Model:
The packaged connector attach to patient thoracic catheters size 8-45Fr.
The pleural collection chamber is graduated in 1 ml increments up to 1 ml and 2 ml increments up to 200 ml.

The Oasis 3650 and 3652 ATS Model:
Pre-attached connectors attach to patient thoracic catheters size 24-40Fr.
The first collection column is graduated in 10 ml increments up to 1100 ml.
Column two is graduated in 10 ml increments from 110 ml up to 2100 ml.
Fluid level graduations are accurate within ±5% at each.

Changes in Patient Pressure
With suction on, patient pressure will equal suction control setting A plus the height of water seal column level B. To graph drainage for 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.

Sampling Drainage
Must be in accordance with approved hospital infection control standards. Selected models include a needlessly Luer port on the patient tube connector for sampling drainage. Aseptic technique required. Do not puncture patient tube until the port is attached to the syringe. Samples can also be taken directly from the patient tube by inserting a 20 gauge (0.81 mm) needle or smaller with syringe. Alcohol swab patient tube prior to inserting syringe needle at a shallow angle.

Storage
Normal room-temperature conditions.

System Disconnection
Clamp off patient and all remaining 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.

Patented by the following International and United States patents: <http://patents.maquet.com>

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Symbols Used On Product Labels

CAUTION DO NOT RE-USE DO NOT RESTERILIZE USE-BY DATE

STERILE FLUID PATH STERILIZED USING ETHYLENE OXIDE NON-PROBING

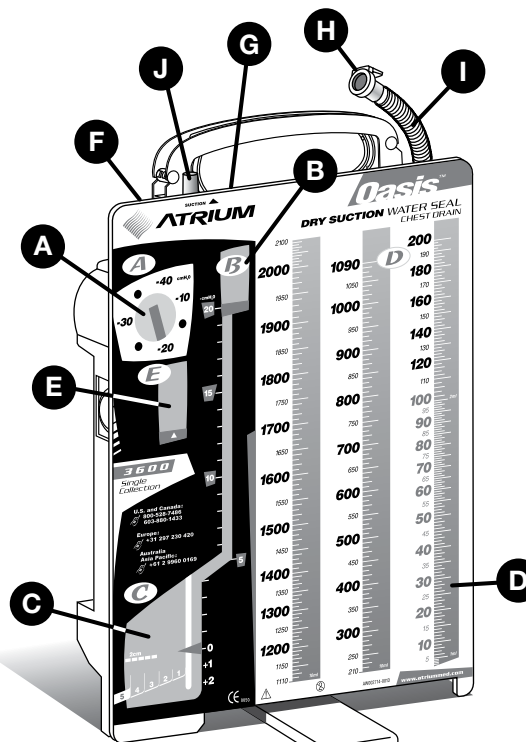
HANDLE WITH CARE HELP 200

DO NOT USE IF PACKAGE IS DAMAGED CONSULT INSTRUCTIONS FOR USE

CAUTION: FEDERAL LAW (BSA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY MANUFACTURER

PLEASE REEL HERE TO OPEN



en

- 1. Suction Control Regulator
- 2. Water Seal Chamber
- 3. Luer Lock Monitor
- 4. Collection Chamber
- 5. Suction Monitor Bellows
- 6. Positive Pressure Release Valve
- 7. Manual High Negativity Vent
- 8. In-Line Connector
- 9. Patient Tubing
- 10. Suction Port
- 11. Regulator of Suction
- 12. Chamber in order to seal
- 13. Collector
- 14. Air Filter of Air
- 15. Access Monitor Bellows
- 16. Water Seal Chamber
- 17. Suction Monitor
- 18. Positive Pressure Release Valve
- 19. Manual High Negativity Vent
- 20. In-Line Connector
- 21. Patient Tubing
- 22. Suction Port

es

- 1. Regulador de control de aspiración
- 2. Cámara de sellado de agua
- 3. Monitor de fugas de aire
- 4. Cámara de succión
- 5. Sello de membrana
- 6. Válvula de liberación de presión positiva
- 7. Válvula manual de alta negatividad
- 8. Conector en línea
- 9. Tubos de paciente
- 10. Puerto de aspiración
- 11. Regulador de control del aspiración
- 12. Cámara de cierre de agua
- 13. Monitor de fugas de ar
- 14. Cámara de succión
- 15. Cámara de membrana
- 16. Válvula de escape de presión positiva
- 17. Válvula manual de alta negatividad
- 18. Conector en línea
- 19. Tubos del paciente
- 20. Puerto de aspiración

nl

- 1. Zuigkrachtregulator
- 2. Waterdichtingskamer
- 3. Leukemonitor
- 4. Opsamelingkamer
- 5. Zuigmonitorklep
- 6. Positieve overdrukklep
- 7. Handmatig bedrukte ventiel voor hoge negatieve vacuüm
- 8. Inlijnconnector
- 9. Patiëntslang(en)
- 10. Zuigpoort
- 11. Regulator van de controle van de aspiratie
- 12. Kamer die water dicht maakt
- 13. Monitor van lekkages
- 14. Opsamelingkamer
- 15. Membranzegel
- 16. Manueel ventiel voor hoge negatieve vacuüm
- 17. Inlijnconnector
- 18. Patiëntslang(en)
- 19. Zuigpoort

fi

- 1. Vuonalaatuksäädä
- 2. Vedenpitäin
- 3. Leukemittari
- 4. Imäyskammio
- 5. Imäyskappale
- 6. Positiivinen painevähdä
- 7. Manuaalinen korkeapainevähdä venttiili
- 8. Suora liitin
- 9. Potilasslangat
- 10. Imäyspöytä
- 11. Vuonalaatuksäädä
- 12. Vedenpitäin
- 13. Leukemittari
- 14. Imäyskammio
- 15. Imäyskappale
- 16. Manuaalinen korkeapainevähdä venttiili
- 17. Suora liitin
- 18. Potilasslangat
- 19. Imäyspöytä

pl

- 1. Regulacja siły ssania
- 2. Izolacja szczelnosci wodnej
- 3. Monitor wyciekow powietrza
- 4. Komora kolekcji
- 5. Klapka monitorujaca
- 6. Zawór zwalniajacy
- 7. Zawór regulujacy
- 8. Wykrywacz przeciekow
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- 19. Wykrywacz przeciekow

ar

- 1. منظم الضغط في الشفط
- 2. غرفة ختم المياه
- 3. مراقب التسرب
- 4. غرفة السحب
- 5. غرفة مراقبة الضغط
- 6. صمام تخفيف الضغط
- 7. صمام التحكم في الضغط
- 8. صمام تخفيف الضغط
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- 19. صمام تخفيف الضغط

ko

- 1. 흡입 조절 장치
- 2. 수분 차단 챔버
- 3. 누출 감지 모니터
- 4. 흡입 챔버
- 5. 흡입 모니터 벨로우즈
- 6. 양압력 릴리프 밸브
- 7. 수직 연결기
- 8. 환자 튜빙
- 9. 흡입 포트
- 10. 흡입 조절 장치
- 11. 수분 차단 챔버
- 12. 누출 감지 모니터
- 13. 흡입 챔버
- 14. 흡입 모니터 벨로우즈
- 15. 양압력 릴리프 밸브
- 16. 수직 연결기
- 17. 환자 튜빙
- 18. 흡입 포트

ru

- 1. Регулятор всасывания
- 2. Водонепроницаемая камера
- 3. Датчик утечки воздуха
- 4. Приемная камера
- 5. Клапан мониторинга
- 6. Клапан сброса давления
- 7. Вертикальный соединитель
- 8. Трубки пациента
- 9. Приемный порт
- 10. Регулятор всасывания
- 11. Водонепроницаемая камера
- 12. Датчик утечки воздуха
- 13. Приемная камера
- 14. Клапан мониторинга
- 15. Клапан сброса давления
- 16. Вертикальный соединитель
- 17. Трубки пациента
- 18. Приемный порт

tr

- 1. Aspirasyon Kontrolü
- 2. Su Sızdırmaz Kamara
- 3. Hava Kaçık Monitörü
- 4. Toplama Odası
- 5. Aspirasyon Monitörü
- 6. Aspirasyon Monitörü
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- 18. Aspirasyon Monitörü

