



English

Operating Instructions

ATMOS

Dressing Kit

REF 314.0004.0
REF 314.0005.0
REF 314.0006.0
REF 314.0007.0

Issue: 09 / 2009-01





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1.1 Scope of supply

- Prior to dispatch, this ATMOS Dressing Kit has been carefully packed. Nevertheless, please compare the contents of the shipment on completeness immediately upon receipt (see delivery note).

REF# 314.0004.0 with 10 FR Round Drain	
REF# 314.0006.0 with 15 FR Cannel Drain	
REF# 314.0007.0 with 10 mm flat Drain	
Drain	1
Transparent Dressing 1.75 x 2.75 in	1
Transparent Dressing 8 x 10 in	1
Skin sealant wipe	1
Saline 0.9 %, 10 ml	2
Oil-Emulsing Non Adhering Dressing 3 x 8 in	1
Gauze	1
Stomahesive Paste	1
Tape Strips	4
Ruler	1
Instruction for Use	1

REF# 314.0005.0 with 19 FR Round Drain	
Drain	1
Transparent Dressing 1.75 x 2.75 in	3
Transparent Dressing 8 x 10 in	3
Skin sealant wipe	2
Saline 0.9 %, 10 ml	4
Oil-Emulsing Non Adhering Dressing 3 x 8 in	3
Gauze	1
Stomahesive Paste	1
Tape Strips	4
Ruler	1
Instruction for Use	1



1.2 Intended use

The ATMOS Dressing Kits are packages of components used to drain off the Wound liquids, to disperse the applied vacuum, generated by an external vacuum source and keep the wound moist.

The ATMOS Dressing Kit is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/neuropathic ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Explored fistulas
- Skin flaps and grafts

1.3 Contraindications

The use of the ATMOS Dressing Kit is contraindicated in the presence of:

- Eschar
- Untreated osteomyelitis
- Malignancy in wound (with exception of palliative care to enhance quality of life)
- Untreated malnutrition
- Exposed arteries, veins or organs
- Necrotic tissue
- Non-enteric unexplored fistulas
- Exposed nerves
- Exposed anastomotic site
- Exposed bone or tendons
- Exposed vasculature

Not to be used:

- In non-medical applications

For your safety



Do not use a Dressing Kit, when the packaging is damaged! The Components are not longer sterile!



All Components of the Dressing Kit are intended for single use. It is forbidden to use the kit twice. ATMOS ist not responsible for any damages or disadvantages to people or goods if:

- the information in these operating instructions are disregarded
- the product is used against its intended use.



Sterile goods are excluded from return/exchange.

1.4 Warnings

1. Bleeding and hemorrhage risk may increase for patients who are receiving anticoagulant therapy or who suffer from compromised hemostasis. NPWT patients should be closely monitored for sudden or increased amount of bleeding at the wound site or in the collection jar.

If increased bleeding is observed, discontinue NPWT immediately and take appropriate action to stop bleeding. Immediately contact medical personnel for further advice or assistance. Where applicable, avoid hemostatic products during therapy which may increase the risk of bleeding.

2. Do not utilize the ATMOS Dressing Kit directly on any exposed blood vessels or organs. Osteomyelitis bone infection sites should be treated first before ATMOS Dressing Kit placement.

3. Prior to using the ATMOS Dressing Kit, please remove or cover a wound's sharp edges or bone fragments. This will avoid the risk of puncturing critical organs and/or blood vessels including vascular anastomosis repairs, when pump is in negative pressure operational mode.

4. If patient defibrillation is needed, please remove all dressing kit items before defibrillation. Failure to do so may delay or prohibit proper patient resuscitation.

5. The ATMOS Dressing Kit has not been evaluated for pediatric patients. Before prescribing this device, determine adequate patient size and weight.

6. Appropriate universal precautions should be observed and implemented when operating, transporting or disposing of the ATMOS Dressing Kit or its accessories. The risk of infectious materials being aspirated or contamination of the pump assembly through incorrect use cannot be eliminated.

7. Some patients have increased risk of bleeding complications that, if uncontrolled, may be fatal. The following patient types are at increased risk:

- Patients who have wounds that have within or surrounding them weakened or fragile blood vessels/organs due to, but not limited to:

- Suturing of the blood vessel (native anastomosis or grafts)/organ
- Infection
- Trauma
- Radiation

- Patients with compromised wound hemostasis
- Patients who have been administered anticoagulants or platelet aggregation inhibitors
- Patients who have limited tissue coverage over vascular structures.

8. Dressing kits should not come into direct contact with tendons, ligaments, nerves and fragile vessels but can be covered with natural tissue, meshed non-adherent material, or bioengineered tissue to help minimize risk of dehydration or injury.



1.5 Precautions

1. Patient precautions for those who are, may be or have:

- Taking anticoagulant therapy; receiving platelet aggregation inhibitors; have weakened blood vessels or organs; who have active bleeding issues
- Impaired wound hemostasis
- Suffering malnutrition
- Non-compliant or aggressive
- Wounds close to blood vessels or delicate fascia

2. Therapy should remain ON for the entire treatment period. Wound dressing components should only be left in place while active NPWT is occurring. Make sure dressing gauze is not retained in wound.

3. Infected wounds oftentimes require more frequent dressing changes. Thus, regular monitoring of the wound is required to check for signs of infection.

4. Do not apply skin sealant wipes directly onto an open wound.

5. Position the ATMOS Dressing Kit and tubing set securely and safely. Avoid tubing trip hazard or tubing occlusion due to a patient lying on or pinching the tubing.

6. It is important that the tubing is installed properly and without kinks to avoid leaks in the suction mechanism.

8. This dressing should only be used by qualified and authorized personnel. The user(s) must be adequately trained, have knowledge and understanding of the specific medical application for which the ATMOS Dressing Kit is being utilized.

9. Dressing kits should not be placed near the vagus nerve, in order to minimize the risk of bradycardia.

10. NPWT therapy should be discontinued if a patient experiences a sudden elevation in blood pressure or heart rate in response to stimulation of the sympathetic nervous system. Seek immediate medical assistance if this occurs.

11. Use of a skin preparation product to protect periwound skin may be applicable. Additional drape, hydrocolloid or other transparent film may help protect the fragile periwound skin.

- Increased risk of maceration may result from utilization of multiple layers of the drape which may decrease the moisture vapor transmission rate.
- Discontinue use and consult a physician if any signs of irritation or sensitivity to the drape, gauze or tubing assembly appear.
- Do not stretch or pull the drape over the dressing while securing it during drape application. This will avoid or minimize trauma to the periwound skin.
- Added caution should be utilized for patients with neuropathic etiologies or circulatory compromise.

12. Use of circumferential negative pressure devices should be avoided. In these situations a circumferential drape may be necessary to establish and/or maintain a seal. It is very important to systematically and frequently palpate distal pulses and assess distal circulatory status. If circulatory compromise is suspected, discontinue therapy, remove dressing components and contact a medical professional.

13. To reduce the risk of infection and the transmission of bloodborne pathogens, apply standard precautions for infection control with all patients and caregivers, per institutional protocol or other approved written guidelines, regardless of the patient's diagnosis or presumed infection status. Use personal protective items such as gloves, smock/gown and face/eye protection if exposure to body fluids or if handling contaminated equipment is probable.

14. Continuous NPWT therapy is recommended for unstable structures, i.e., unstable chest wall or non-intact fascia rather than intermittent NPWT therapy. This helps to reduce movement and stabilize the wound bed. Continuous NPWT therapy is commonly recommended for patients at increased risk of bleeding, exudating or acute enteric fistulae wounds, and fresh flaps/grafts.

1.6 Physician Orders

The ATMOS Dressing Kit is indicated for patients who would benefit from this type of Negative pressure Wound Therapy treatment. Physician orders should include the following:

- Wound locations, size with depth and length
- Dressing kit types and frequency of use
- Pressure settings for suction pump in mmHg

United States of America Federal Law prohibits the use of this device without a prescription!



2.1 Standard Precautions

Standard Precautions are intended to prevent the transmission of common infectious agents to healthcare personnel, patients and visitors alike. While in the presence of a patient, one should assume that an infectious agent could be present in the patient's bodily fluids, therefore, requiring appropriate precautions.

Therefore, to reduce the risk of infection and the transmission of bloodborne pathogens, apply standard precautions for infection control with all patients and caregivers, per institutional protocol or other approved written guidelines, regardless of the patient's diagnosis or presumed infection status. Use personal protective items such as gloves, smock/gown and face/eye protection if exposure to body fluids or if handling contaminated equipment is probable (see chart below):

Gloves

Use when touching blood, body fluids, secretions, excretions, contaminated items, and for touching nonintact skin and mucous membranes.

Face/Eye Protection

Use during patient care that may generate splashes, sprays of blood, body fluids secretions and excretions.

Smock/Gown

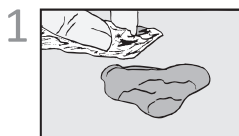
Use for procedures and patient care activities when contact of clothing and/or exposed skin with body fluids is expected.

Hand Hygiene

Wash hands thoroughly with soap and water or use an alcohol based hand prep. Wash hands immediately after removing personal protective equipment and between patient contacts.

3.1 Typical use of wound drainage kit according to Chariker-Jeter¹

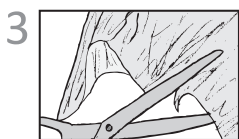
Clean the wound bed according to your company's protocol.



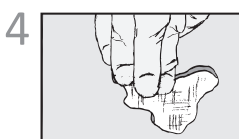
Apply skin sealant to the area surrounding the wound bed. Optional: You may treat the edges of the wound with hydrocolloids for a better seal.



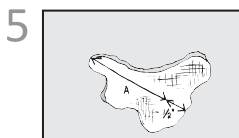
Cut the non-adherent dressing to the size of the wound



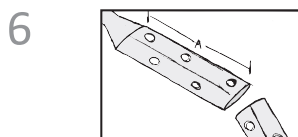
Lay the non-adherent dressing across the entire wound bed.



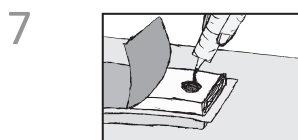
Measure the base of the wound, subtracting approximately a half inch from the tube length.



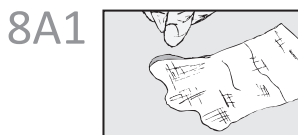
Cut the drain according to the adjusted measurement you have taken from the base of the wound.



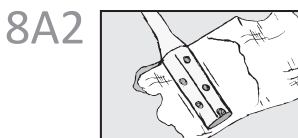
Open the antimicrobial gauze and saturate with saline solution.



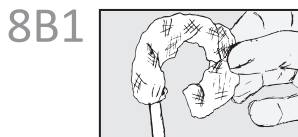
NOTE: 8A is applicable for flat or round drains
Place saline saturated gauze on the wound bed.



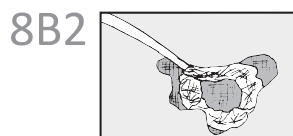
Position shortened drain on top of gauze.



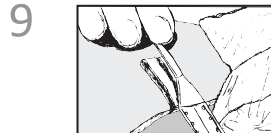
NOTE: 8B is applicable for channel drains
If preparing a channel drain, wrap the saline saturated gauze around the shortened drain.



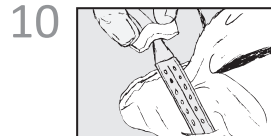
Position the wrapped channel drain on top of gauze.



Place a portion of the ostomy strip on the edge of the wound and fixate drain.



Use the remaining piece of ostomy strip to cover the top of the fixated drain.



Place saline saturated gauze over top of drain to produce a full wound bed.



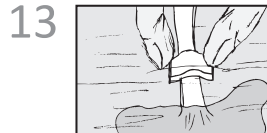
Be careful not to overpack the wound bed.



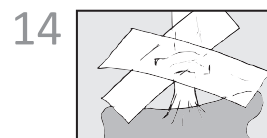
Place transparent film dressing over the wound, leaving at least a one inch border to ensure a proper seal.



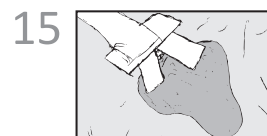
Ensure a proper seal around the drain tube by pressing the film onto the ostomy strip.



Where the drain tube exits the transparent film, apply two strips of waterproof tape in an X formation to keep the film airtight.



The dressing should contract noticeably. If it does not, check the dressing for a leak.



¹ Chariker ME, Jeter KF, Tittle TE, Bottsford JE. „Effective management of incisional and cutaneous fistulae with closed suction wound drainage.“ *Contemp Surg.* 1989; 34:59.
Jeter, Katherine. Closed Suction Wound Drainage Systems. *Journal of Wound Ostomy and Continence Nursing.* March/April 2004, Volume 31 number 2, pages 51:57

ATMOS General Standard Terms and Conditions

1. General:

Our General Standard Terms and Conditions apply exclusively. Client's terms and conditions which are contrary to or deviate from our General Standard Terms and Conditions are not recognised unless their validity is explicitly confirmed in writing. Our General Standard Terms and Conditions also apply even if we deliver to clients without reservation, in the knowledge of the client's contrary terms and conditions. Our General Standard Terms and Conditions also apply to all future business with that client.

2. Proposal - Order Confirmation

Our proposals are subject to change without notice unless otherwise stated in our order confirmation. Each order is only accepted by us following our written order confirmation.

3. Orders

Every order requires an exact description of all of our product's details. We assume no liability for errors and damage caused by inaccurate or incomplete ordering details.

4. Prices

Unless otherwise stated in the order confirmation, our prices in the order confirmation are ex factory prices and exclude packaging and value added tax. Packaging is charged separately at cost price in the invoice. Value added tax is charged separately in the invoice according to the legal rate on the invoice date. We reserve the right to change prices appropriately should price reductions or increases, especially due to wage settlements, changes in the price of materials or currency fluctuations, be incurred. Proof of such changes will be provided for the client on request.

5. Payment Conditions - Balancing

Unless otherwise stated in the order confirmation, our invoices are payable with a 3% discount within 10 days (except for repair and assembly services) or within 21 days from the invoice date net cash; money receipts is decisive for complying with this term. We are entitled to charge interest after the due date at a rate 2% above the relevant basic interest rate of the German Federal Bank. Should the client have payment arrears, we are entitled to charge interest on arrears at a rate 5% above the relevant basic interest rate of the German Federal Bank. Should we be able to prove higher damages due to arrears, we are also entitled to claim these. The client only has the right to balance invoices against its own claims should such claims be confirmed in a court of law or recognised by us. The client does not have the right of retention due to disputed counterclaims.

6. Delivery Periods

Fulfillment of our delivery duties requires the punctual and proper fulfillment of the client's duties. The right to defense on the grounds of an unfulfilled contract is reserved. Should the client default in accepting the goods delivery or breach other cooperation duties, we are entitled either to withdraw from the contract or claim compensation for any increased costs incurred up to that time without setting a further deadline. The right to make further claims is reserved. Furthermore, in such cases, the risk of coincidental destruction or a coincidental deterioration in the quality of the delivered goods is transferred to the client in the case of default in accepting such goods or payment arrears. Acts of God or stoppages (due to insufficient supplies of material, industrial disputes etc.) entitle us either to demand an appropriate extension of delivery periods or to partly or entirely dissolve the delivery contract. This does not give the client the right to claim damages. We have fulfilled delivery periods if the delivery goods have left our factory or the client has been informed of the goods' readiness for delivery within such delivery periods. Delivery periods stipulated by the client are not recognised by us unless they form part of our order confirmation. We adhere to legal terms and conditions in cases where, as a result of an undue delay in the delivery for which we are liable, the client is entitled to claim that his interests in a continued fulfillment of the contract have ceased. We also adhere to legal terms and conditions should a delay in delivery be caused by deliberate or grossly negligent action by us or our representatives for which we are responsible. We are also responsible for such actions by our representatives or agents. Should the delivery delay not be caused by our deliberate infringement of contractual duties for which we are responsible, our liability is limited to damage which is regarded as typical for that case. We are liable according to the legal terms and conditions if and in so far as the delivery delay for which we are responsible is caused by an infringement of a substantial contractual duty. In such cases, our liability is also limited to damage which is regarded as typical for that case. Should the delivery delay be caused by a culpable infringement of non-substantial contractual duties, our client is also entitled

to claim a one-off damage compensation worth 3 percentage points of the delivery value of the goods for each week's delay, up to a maximum which is no higher than 15 percentage points of the delivery value of the goods

7. Delivery - Familiarisation

In the case of the delivery of devices for the medico-technical industry which require assembly and/or familiarisation for the final customer using specialist trade personnel (such as Ear, Nose and Throat Apparatus and Suction Units), we reserve the right to deliver the goods exclusively to the relevant specialist traders. Should the trader not carry out assembly and/or familiarisation for the final customer, this is carried out by us. In such cases, we reserve the right to charge the client for the additionally created costs. Our specialist traders operate a recording system so that, if necessary, our products can be traced to the final customer. The specialist trader undertakes to immediately report to us all events and risks which must be reported in connection with our products.

8. Passage of Risk - Packaging

Unless otherwise stated in our order confirmation, delivery is agreed ex factory. The risk of the goods' damage or loss is therefore transferred to the client as soon as the goods leave the factory or the client is in default of acceptance of the goods. This also applies to cases where we confirm prepaid carriage. Transport packaging and all other packaging according to the packaging regulations is not returnable. Our client is responsible for disposing the packaging at its own cost. Our deliveries are insured by us at the client's expense unless explicitly otherwise agreed. No insurance is arranged in the case of goods which are collected by our clients. In the case of transport damage, claims are only handled if the client receives confirmation of any damage, reduced weight or loss by the shipping company before accepting the delivery.

9. Warranty

The client is responsible for examining the delivered goods immediately after receiving them to determine any eventual deficiencies or delivery errors, and to report these immediately. Should the client fulfil this examining and reporting responsibility, and should payment conditions be fulfilled, we shall be liable to the client within the scope of legal regulations. Our period of warranty shall in all cases be two years. Our client can make use of the warranty as follows, so long as he can provide first buyer proof (in the form of an invoice or delivery note) and provided that the product still has the original, unchanged serial number:

a. We choose whether to fulfil our guarantee by providing repair services free of charge - either on the client's premises or in our factory - or replacing the product. We can also provide these guarantee services through an authorised company;

b. Should a product be returned to us, the client agrees to send the product in its original or similar packaging, offering the same protection as the original packaging, to our address or any address notified by us.

c. Our guarantee ceases to apply if changes of any kind have been made to our product, unless such changes have been made by us or a company authorised by us, or have been previously agreed upon in writing by us. Our guarantee also ceases to apply if third parties have carried out repairs to our products or replaced parts thereof. This applies regardless of the fact whether these measures individually or collectively led to a deficiency of the product;

d. We accept no responsibility for damage defects caused by

- operational wear and tear;
- incorrect installation or incorrect or insufficient maintenance;
- incorrect operation of the product (in contradiction to the handbook delivered with the product);
- improper use or operating faults;
- inappropriate or negligent handling and care, especially with respect to dirt, lime, suction of fluids, inappropriate cleaning and sterilisation;
- using accessories and/or replacement parts which are not explicitly approved;
- incorrect assembly and/or initial operation by the client or third parties;
- the client's negligence in handling the product;
- unacceptable operating conditions, such as humidity, temperatures, the power supply, vibrations.

- accidents, acts of God, especially lightning, water, fire, public unrest and insufficient ventilation. We are not liable for damage to other objects apart from our product itself, except in the case of any deliberate or grossly negligent actions by us or our representatives or agents. Should no deliberate breach of contract be claimed, our liability is limited to damage which is regarded as typical for that case. This also applies in the case of our culpable infringement of substantial contractual duties. The indispensable conditions of German Liability Law remain unaffected thereby.

- For second-hand equipment, the period of warranty shall be reduced to a period of twelve months.

10. Reservation of Ownership

We retain ownership of our goods until the receipt of all payments arising from the business relationship, including all demands arising from installation orders, subsequent orders, repairs, accessory deliveries and replacement orders. Should we have agreed upon payment on the basis of cheque and bill transactions, the ownership reservation applies until the cheque received by us has been paid in, and does not expire through our credit upon receiving the client's cheque. In the case of a breach of contract by the client, especially payment arrears, we are entitled to repossess our goods. Repossession of our goods represents a withdrawal from the contract, unless explicitly declared in writing by us. We have the right to utilise the product after its repossession, whilst the income from such use is balanced against the client's arrears, after deducting appropriate utilisation costs. The client is responsible for handling the goods with care. Should maintenance and inspection work be necessary, the client must carry these out punctually at his own cost. Our client is entitled to sell the goods he has bought from us in a proper sale transaction. However, he must immediately assign all outstanding claims to the value of the final invoice sum (including value added tax) of our claims to his customers or third parties. The client is entitled to collect this claim even after such assignment. Our right to collect the claim ourselves remains unaffected thereby. We undertake to release the securities to which we are entitled if requested to do so by the client should the realisable value of the our securities be more than 10 percentage points higher than the outstanding claims. We reserve the right to choose the securities to be released.

11. Plans and Illustrations

We retain ownership of and copyrights to all plans, illustrations, calculations and other documents which are attached to our proposals. The client must receive explicit written permission before passing these on to third parties. Imitating our legally patented products is forbidden and will be prosecuted.

12. Jurisdiction and Place of Performance

Our central office is the place of performance for all disputes in connection with these General Standard Terms and Conditions and the contracts closed with clients under them. This jurisdiction excludes other jurisdiction relating to persons or subject-matter. Furthermore, our client is not entitled to bring charges against us in another court should he file counter-charges, carry out counterbalancing or declare retention. We, however, are entitled to bring charges against our client at their general place of jurisdiction or at another relevant court recognised by German or foreign law. Unless otherwise stated in the order confirmation, our central office is the place of performance.

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