

Shropshire Community Health

NHS Trust
Policies, Procedures, Guidelines and Protocols

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AVANCE CLINICIAN'S GUIDELINES

LAST UPDATED: SEPTEMBER 2015

SafetaC
TECHNOLOGY

NOTICE TO CLINICIANS

These guidelines are intended for use with the Avance® Negative Pressure Wound Therapy (NPWT) System (Mölnlycke Health Care, Gothenburg, Sweden). The guidelines are for clinical care teams to institute or incorporate into already established wound-specific protocols of care for the patients they treat. The guidelines are not intended as a guarantee of performance or clinical outcome.

As with any medical intervention, please consult with the patient's clinician for specific instructions regarding treatment with this system. Reference should also be made to the instructions for use supplied with the system.

DISCLAIMER

The views expressed in these guidelines reflect the knowledge and experience of the editorial reviewers. Mölnlycke Health Care has made every effort to ensure the accuracy of the information contained in these guidelines. However, this does not diminish the requirement to exercise clinical judgement, and the company cannot accept any responsibility for the use of the information in clinical practice. All products referred to in the guidelines should be used according to the recommendations of the manufacturer.

STATEMENT FROM EDITORIAL REVIEW BOARD

Negative Pressure Wound Therapy (NPWT) is now well established as a means of treating a variety of different wound types. The evidence appears to suggest that NPWT has a number of clinical effects which aid in promoting a healing response, i.e.:

- Stimulation of wounds that have previously failed to heal
- Initiation of wound size reduction, thereby stimulating contraction and granulation tissue formation to a point where another therapy can be used to complete the wound healing
- Removal of wound exudate, which helps to promote an optimal wound healing environment and assist with controlling peri-wound skin maceration
- Reduction in bacterial colonisation by continually removing exudate
- Removal of soft, sloughy tissue.

The Avance NPWT System (Mölnlycke Health Care) has been developed as a flexible and easy-to-use treatment that helps to promote wound healing, including drainage and removal of infectious material or other fluids, under the influence of constant and/or intermittent negative pressure. The Avance Pump is lightweight (less than 1kg) and comes with a unique docking station, giving patients greater mobility either in hospital or at home. It can be used with a choice of dressing kits, depending on the wound and patient's needs. Avance is the only NPWT system that offers products with Safetac®, a unique technology clinically proven to minimise dressing-related pain and trauma. These unique products include Avance Film with Safetac technology, Mepiseal®, Mepitel® and Mepitel® One. Avance is designed to maximise the benefits of NPWT by minimising the unnecessary suffering.

This document has been developed to provide the most up-to-date information to assist clinicians in using the Avance NPWT System in specific clinical circumstances.

The contents of this document have been reviewed and approved by the clinicians listed overleaf, who are experts in using NPWT.

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INTRODUCTION

INTRODUCTION TO NEGATIVE PRESSURE WOUND THERAPY (NPWT)

NPWT has gained rapid acceptance by physicians and plastic surgeons in the management of acute and hard-to-heal wounds.¹ The delivery of NPWT to the wound takes two forms, each of which was developed independently, with the major difference between them being the type of dressing used: foam² or gauze.³

It has been shown that NPWT enables drainage of excess fluid and debris from the wound to which it is applied and that it induces mechanical deformation of the wound edge tissue.^{2,4,5} Furthermore, NPWT creates a moist wound healing environment⁶ which helps to encourage the normal wound healing process. The published results of studies indicate that NPWT reduces bacterial load,⁴ increases granulation tissue formation,⁴ reduces oedema,⁷ stimulates cell-mediated immune response,⁸ decreases blood vessel permeability,⁹ and stimulates angiogenesis and blood flow to the wound margins.¹⁰

There is evidence to suggest that NPWT may also help to remove inhibitory cytokines and activated polymorphonuclear leukocytes present in the wound bed. These are responsible, in part, for chronic wounds (more commonly referred to as 'hard-to-heal wounds') becoming suspended in an inflammatory state.¹¹

It is a well-recognised phenomenon that patients with chronic wounds have associated pain. It has also been identified that dressing changes can cause the most pain and discomfort for these patients.¹² Patients with acute wounds may also experience pain at dressing change and careful dressing selection can help to reduce the level of pain endured during the procedure. Clinicians still encounter difficulties in assessing patient pain and having protocols in place to deal with it.¹³ This is despite the World Union of Wound Healing Societies (WUWHS) developing specific guidance for the assessment and management of patients with wound pain.^{14,15} The WUWHS guidance clearly states that "the goal for all wound types is to minimise pain and create optimal conditions for wound healing".¹⁵ Wound healing can be disrupted when pain is present, if the patient becomes stressed thinking about their dressing change, or during the dressing change.¹⁶ By assessing pain before each dressing change, clinicians can help to prevent pain by selecting appropriate analgesics and using atraumatic dressings.¹⁷ NPWT is one of the most successful treatments for effective wound healing. Some research has indicated that patients experience pain during NPWT dressing changes.^{18,19}

Patient quality of life can be affected during NPWT. It has been reported that some patients find this treatment embarrassing, from the noise, exudate smell and the impact of carrying the pump.²⁰ Furthermore, the NPWT system can cause patients to feel anxious due to both the patient and the health professional being unfamiliar with this form of treatment. It can also restrict patients' daily care and wider social life, which may result in a negative self-image and low self-esteem.²¹ Others have found that NPWT has a positive effect on their life and allows for a sense of control.²² Rafter (2011) quoted that NPWT resulted in an improved quality of life for one patient with three complex wounds.²³

All circumstances need to be assessed for each patient prior to commencement of NPWT. Appropriate patient selection with a clear aim of treatment should be established. An NPWT system offering less pain and less trauma can assist in optimising wound healing.

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Patients' experiences of negative pressure wound therapy for the treatment of wounds: a review. *J Wound Care* 2013;22(1):34-39. 22. Moffat, C.J., et al. The experience of patients with complex wounds and the use of NPWT in a home-care setting. *J Wound Care* 2011;20(5):214-216. 23. Rafter, L. Assessing a new negative pressure wound therapy (NPWT) system in clinical practice. *Wounds UK* 2011;7(4):112-120.

DESCRIPTION OF THE AVANCE NPWT SYSTEM

The Avance NPWT System is a flexible and easy-to-use treatment that helps to promote wound healing, including drainage and removal of infectious material or other fluids, under the influence of constant and/or intermittent negative pressure.

Avance products with Safetac® technology

Avance is the only NPWT system that offers products with Safetac, a unique technology clinically proven to minimise dressing-related pain and trauma. These unique products (Avance Film with Safetac, Mepiseal®, Mepitel® and Mepitel® One) help to achieve and maintain effective NPWT whilst minimising the risk of dressing-related trauma and pain. Avance NPWT system is designed to maximise the benefits of NPWT by minimising unnecessary patient suffering.

Safetac technology

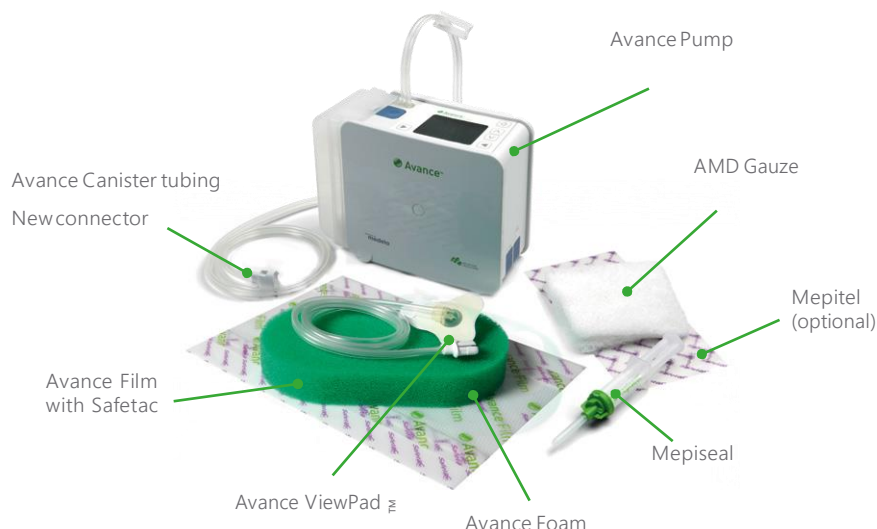
Safetac is a patented soft silicone adhesive technology that minimises pain to patients and trauma to wounds. Safetac technology minimises pain because it:

- Tacks gently to dry surfaces like skin, but not to moist surfaces like open wounds
- Moulds to the skin's pores, covering more skin surface and spreading peel forces on removal to prevent skin stripping
- Seals the wound margins, ensuring exudate does not spread to the surrounding skin and minimising the risk of maceration.

Dressing kits

Dressing kits contain either foam or gauze; this allows clinicians to select the most suitable dressing for the wound type being treated. Kits also contain one of two types of film for helping to maintain a closed wound environment - Avance Transparent Film or Avance Film with Safetac. Foam dressing kits are available with and without Mepitel with Safetac, which can be applied to the wound bed to reduce the discomfort on dressing removal or to protect exposed organs from the direct positioning of NPWT.

The Avance NPWT system with Safetac technology



Avance Pump

The Avance Pump is lightweight (less than 1kg) and comes with a unique docking station, giving patients greater mobility either in hospital or at home. It can be used with a choice of dressing kits, depending on the wound and patient's needs. The Avance Pump is capable of delivering constant or intermittent NPWT across a range of -40mmHg to -200mmHg. It also incorporates Dynamic Exudate Management, intelligent pump software, which monitors wound exudate levels. Depending on the level of exudate, the software adjusts its flushing cycles in order to transport the exudate towards the canister, and alerts clinicians to any problems associated with the delivery of NPWT. The Avance Pump can be programmed for use in different languages.

Avance Canister

There are two canister sizes available for use with the Avance NPWT System (300ml or 800ml). The canisters are sterile, single-use devices and contain a component that solidifies wound exudate.



AvanceCanister Tubing

The tubing incorporates a specially designed double lumen for fluid evacuation. At one end of the canister tubing, there is a connector into the Avance Pump. At the other end is a secure connector which fits directly to the ViewPad, the drain adaptor or the Y-connector.



Avance Tube Cover

This elasticated tube cover can be placed over the length of the Avance Canister Tubing to make it more discreet for patients.



AvanceCarrying Case

This is a single-patient-use case that enables patient mobilisation with the Avance Pump and a 300ml canister attached.



AvanceDocking Station

The unique docking station enables easy recharging of the Avance Pump.



Avance Foam

The green-coloured Avance Foam is a hydrophobic reticulated polyurethane foam with a large open cell structure. It is intended for use in the Avance NPWT System to distribute the pressure across the wound surface and allow passage of fluids and exudate through to the negative pressure system. The colour of the foam dressing enables easy visualisation of bleeding and exudate. The foam is available in small, medium, large and extra large size dressing kits.



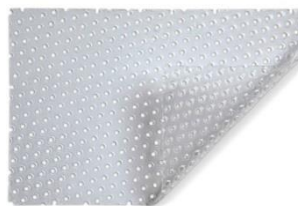
Kerlix® AMD® Antimicrobial Super Sponges (AMD Gauze)

The gauze antimicrobial dressing (AMD) is intended for use as a primary dressing for a range of wounds to distribute the pressure across the wound surface and allow passage of fluids and exudate through to the negative pressure system. The inclusion of polyhexamethyl biguanide (PHMB) in these dressings helps resist bacterial colonisation of the dressings and inhibit bacterial penetration through the dressings. The gauze is available in small, medium, large and extra large size dressing kits.



Mepitel®

Mepitel is a porous, transparent and flexible polyamide net with open mesh structure, coated on both sides with Safetac®, a patented soft silicone adhesive technology. Mepitel One is another transparent wound contact layer but differs from Mepitel in that it is only coated on one side (the wound contact surface) with Safetac. When clinically indicated, Mepitel /Mepitel One is applied to the wound bed to minimise pain and prevent trauma on dressing removal or to protect exposed fragile tissues from the direct positioning of NPWT.



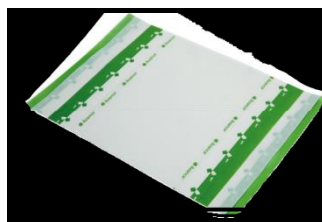
Avance Film with Safetac

Avance Film with Safetac consists of a Safetac skin contact layer and a backing film which is vapour-permeable and waterproof. It is intended for use with the Avance NPWT System to fixate the wound dressing and provide an adequate seal. The film is designed to minimise pain and prevent trauma at dressing change. The Safetac skin contact layer facilitates repositioning of the film dressing.



Avance Transparent Film

Avance Transparent Film is a thin, transparent and breathable polyurethane film coated with a polyacrylic adhesive. The film is intended for use with the Avance NPWT system to fixate the wound dressing and provide an adequate seal.



Avance Flat Drain

Used to transport exudate to the Avance Pump, the soft and flexible flat drain is ideal for use on a majority of different wound types, in conjunction with gauze wound dressings. The silicone drain is radiopaque, thereby enabling X-ray detection.



Avance Round Drain

Used to transport exudate to the Avance Pump, the round drain can be used on a variety of wound types, but is particularly suited for wounds with tunnelling and undermining. The silicone drain is radiopaque, thereby enabling X-ray detection.



Avance ViewPad 2

This pad is intended to distribute pressure to the wound bed and facilitate transfer of fluids and exudate from the wound to the canister



Avance Y-connector

This connector allows two appropriate wounds, on the same patient, to receive negative pressure using one pump.



Mepiseal® with Safetac®

Mepiseal is a non-sterile, viscous silicone that forms into a sealant directly after application. When used in conjunction with NPWT, Mepiseal can help to achieve an initial seal and maintain a seal in-between dressing changes to ensure a constant and accurate delivery of negative pressure to the wound. The inclusion of Safetac technology in the design of Mepiseal assures minimisation of pain at application, during use and at removal. Mepiseal is easily removed (i.e. it comes off with the dressing that it is used under) and leaves no residue on the skin.



INDICATIONS

Published literature indicates that NPWT has been most commonly applied to the following:

- Acute wounds¹
- Burns requiring skin grafts^{2,3}
- Venous or arterial insufficiency ulcers⁴
- Traumatic wounds (i.e. flap or meshed graft)⁵
- Pressure ulcers^{6,7}
- Diabetic foot ulcers and partial foot amputations^{8,9}
- Chronic leg ulcers¹⁰
- Chronic open wounds¹¹
- Flaps and grafts¹²
- Dehiscent surgical wounds^{13,14}
- Sternal wounds¹⁵
- Abdominal wounds¹⁶
- Necrotising fasciitis^{17,18}
-

The Avance NPWT System is indicated for traumatic wounds, surgical (sternal/abdominal/extremity) wounds, dehiscent wounds, chronic wounds (including pressure ulcers, diabetic foot ulcers and venous leg ulcers), partial thickness burns, flaps and grafts.

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presentation at the Wounds UK Conference, Harrogate, United Kingdom, 2010. 15. Simek, M., Hajek, R., Fluger, I., et al. Superiority of topical negative pressure over closed irrigation of deep sterna wound infection in cardiac surgery. *J Cardiovasc Surg (Torino)* 2012 Feb;53(1):113-120. 16. Kaplan, M. Negative pressure wound therapy in the management of abdominal compartment syndrome. *Ostomy Wound Manage* 2004;50(11A Suppl):20S-25S. 17. Sarani, B., et al. Necrotising fascitis: current concepts and review of the literature. *J Am Coll Surg* 2009;208(2):279-88. 18. Rafter, L. The management of a patient with necrotising facitis employing topical negative pressure. *Wounds UK* 2012;8(4):90-97.

CONTRAINDICATIONS

The information contained within this section is not exhaustive. Please consult the relevant instructions for use prior to using the components of the Avance NPWT System and other products referred to in these guidelines.

Contraindications for treatment with the Avance NPWT System are:

- Direct positioning of NPWT (foam or gauze dressings) over exposed organs, large veins and arteries, anastomotic sites, tendons or nerves
- Malignant wounds*
- Untreated osteomyelitis
- Non-enteric unexplored fistulas
- Wounds with significant amounts of necrotic tissue or eschar present.

* In exceptional circumstances, the Avance NPWT System may be used under close supervision in palliative care.

PRECAUTIONS AND WARNINGS

The information contained within this section is not exhaustive. Please consult the relevant instructions for use prior to using the components of Avance NPWT system and other products referred to in these guidelines.

The following precautions and warnings are applicable for the safe and effective use of Avance NPWT System.

General

- The safe and effective operation of Avance NPWT System requires specific instructions from a clinician
- Avance NPWT is only to be used by persons who have been adequately trained in wound care and the use of Avance NPWT System
- Before the initiation of treatment, the indications, contraindications, precautions and warnings listed in the instructions for use (supplied with Avance NPWT System) should be read and understood. Failure to read and follow all instructions supplied with the system may lead to considerable dangers and cause injury and pain to the patient
- Avance NPWT System is intended for use with patients in healthcare facilities and home care settings by trained medical and healthcare personnel adhering to the instructions for use. Consideration should be given to the patient's hearing function and visual acuity prior to use in home care settings
- Therapy changes (pressure level, constant or intermittent mode) may only be done as prescribed by the patient's clinician.

Clinical

- Avance NPWT System must not be used on the following:
 - Patients who are sensitive to any of its components or related products
 - Patients who are bathing or showering
 - Patients undergoing magnetic resonance imaging (MRI) / tomography examinations
 - Patients receiving hyperbaric oxygen therapy
 - Patients undergoing/receiving investigations/therapies involving microwaves

(e.g. high-energy transurethral microwave thermotherapy)

- Patients in hazardous explosive environments

- There is limited experience of using NPWT on paediatric patients. Clinicians should consider the potential benefits and risk of using NPWT on paediatric patients
- Extra care must be taken with the following:
 - Patients with active bleeding, difficult wound haemostasis, or at risk of bleeding, e.g. those receiving anticoagulant therapy (anticoagulants or platelet aggregation inhibitors). The use of NPWT may increase the risk of bleeding so patients need to be monitored closely during therapy
 - Patients with a history of irradiated or sutured blood vessels or organs
 - Patients with ischaemic conditions (extra monitoring of wound status is required to avoid risk of wound bed deterioration)
 - Treating wounds in close proximity to organs or large veins and arteries
- Before initiating NPWT treatment, the patient's nutritional status should be evaluated and severe malnutrition addressed
- Patients undergoing NPWT need frequent supervision. Signs of possible infection or complications such as fever, pain, redness, increased warmth, swelling and purulent discharge must be addressed immediately. The device, wound, surrounding skin and patient status must be monitored accordingly to ensure sufficient and safe treatment and patient comfort. The frequency of dressing changes may need to be increased if infection is present
- Excessive vacuum, an adhesive dressing applied too taut or an infection of the wound, can cause the patient to experience pain. In each case, the dressing must be changed and the wound thoroughly assessed
- To prevent puncture of blood vessels, protective barriers or organs, and damage to tendons, bones and nerves, sharp edges (e.g. staples) or bone fragments must be eliminated from the wound area or covered with a non-adherent wound contact layer (e.g. Mepitel®/Mepitel® One with Safetac®) prior to using Avance NPWT System
- If bleeding suddenly develops or an ongoing bleed increases during NPWT, immediately discontinue treatment, leave the dressing in place, consult the patient's clinician and take measures to stop the bleeding
- Should the patient experience autonomic hyperreflexia, discontinue treatment with Avance NPWT System and consult the patient's clinician immediately

- If disconnection from the Avance Pump is required (e.g. for showering, medical examinations or other activities), consideration should be given to the amount of time without applied negative pressure and a clinical decision taken accordingly. The decision should be based on an assessment of the bacterial burden of the wound and the risk of infection, as well as the amount of exudate and the integrity of the film seal since exudate may leak onto surrounding skin, causing maceration. Patients should be discontinued from the pump only for short periods of time and for no more than two hours in a 24-hour period. If the NPWT is discontinued for more than two hours in a 24-hour period, then the NPWT dressing should be removed and an alternative dressing should be applied to prevent deterioration of the wound.

Pump

- Mölnlycke Health Care can only guarantee the safe function of the system if Avance Pump is used in combination with the original products included in the Avance NPWT System. Avance Pump is EMC-tested (Electro Magnetic Compatibility) in conformity with the requirements of IEC 60601-1-2 and can be used in the vicinity of other EMC-tested devices that fulfill the requirements of the relevant IEC 60601-1-2 standard. Untested HF (High frequency) sources, radio networks or the like can influence the operation of the device and may not be operated in combination with Avance NPWT System. The warnings, precautions and safety instructions should be read and fully understood before use of the system
- Before the pump is charged, the local power supply must be checked to make sure that it is the same as the voltage given on the pump's specification plate
- Avance Pump must remain in an upright position during use
- Avance Pump must not be dried with microwaves
- Avance Pump is protected against the penetration of solid/fluid substances by a hydrophilic filter. If this filter fails, an alarm will sound then Avance Pump must be replaced.

Dressing kits

- Dressings must not be placed into unexplored or blind tunnels or non-enteric fistulas
- In-growth of tissue into the wound dressing may occur if it is not changed according to recommendations or according to the wound condition of the individual patient
- If more than one piece of NPWT dressing / wound contact layer is used, always count the number of pieces and document the total in the patient's notes. This is to ensure that all pieces are removed when the dressing is changed
- Ensure there is contact between all pieces of NPWT dressing to allow for even distribution of negative pressure
- The NPWT dressing should not be cut over the wound site as fragments could fall into the wound. It is important to check that no fragments are left in the wound when the dressing is changed
- The NPWT dressing should not be over-packed into any area of the wound, as this could damage tissue, impair exudate removal, or affect delivery of negative pressure
- The NPWT dressing should be positioned in the wound and not overlap onto intact skin
- Oxidising agents such as hypochlorite solutions or hydrogen peroxide must not be used prior to the application of Avance Foam
- The presence of topical preparations on the patient's skin, prior to application of the film, can affect the ability of the film to adhere securely
- Stretching the Avance Transparent Film and Avance Film with Safetac technology during application may cause damage to the surrounding skin and loosening of the film when negative pressure is applied
- The presence of silicone adhesive on top of the film, Avance ViewPad™, can affect the ability of the ViewPad to adhere securely
- Blockage of the drain/ViewPad tubing and canister tubing may occur if the tubing is kinked
- The canister tubing supplied with Avance NPWT System must never be placed in the wound
- Consideration should be given to using a protective barrier where drain/tubing comes into contact with fragile or friable skin.

GENERAL WOUND APPLICATIONS

CHOICE OF WOUND DRESSING

The flexibility of the Avance NPWT System allows it to be used with either gauze (AMD Gauze) or foam (Avance Foam) dressings. This gives the clinician the opportunity to select the most suitable dressing for effective NPWT.

CHOICE OF WOUND CONTACT LAYER

If indicated, clinicians have the option of using one of two wound contact layers that incorporate Safetac® technology.

Mepitel®

Mepitel is an atraumatic wound contact layer coated with Safetac on both sides.

Mepitel One

Mepitel One is an atraumatic wound contact layer coated with Safetac on just the wound contact side to facilitate easier handling.

When clinically indicated, Mepitel or Mepitel One can be applied to the wound bed to reduce discomfort on dressing removal or to protect exposed fragile tissues from the direct positioning of foam or gauze.

PREPARATION OF WOUND BED AND PERI-WOUND AREA

- Prior to selecting either type of dressing (Avance Foam or Gauze), the wound and peri-wound skin should be cleansed in accordance with local wound care protocols
- If there is a significant area of necrotic, non-viable tissue (including eschar, fibrin or slough), debridement should be carried out prior to the application of Avance NPWT System in line with local wound care protocols
- Sharp edges or bone fragments must be eliminated from the wound area or covered by a wound contact layer (e.g. Mepitel®/Mepitel One with Safetac®).

APPLYING WOUND CONTACT LAYER

Mepitel® with Safetac®

1. Following adequate wound bed preparation, choose a size of Mepitel that fits the dimensions of the wound bed or the area that needs to be protected. If required, Mepitel can be cut.
2. While holding the larger of the two protective films, remove the smaller one. Moisten gloves to avoid adherence to Mepitel.
3. Apply Mepitel over the wound and remove the remaining protective film. If more than one piece of Mepitel is required to cover the wound, overlap the edges of the dressings. If clinically indicated, more than one layer of Mepitel can be applied.
4. When Mepitel is used in conjunction with Avance NPWT system, it should be changed every 48 to 72 hours, but no less than three times per week, or as instructed by the patient's clinician.*
5. Mepitel can also be used to wrap around a piece of foam before placement into tunnelling or undermining area.

* The clinical indication for the use of Mepitel/Mepitel One with Avance NPWT System is somewhat different from the normal rationale for applying wound contact layers. This is reflected in the need to increase the frequency of dressing change over and above what is normally practiced.

Mepitel® One with Safetac®

1. Following adequate wound bed preparation, choose a size of Mepitel One that fits the dimensions of the wound bed or the area that needs to be protected. If required, Mepitel One can be cut.
2. Remove the protective film by using the overlapping grip edge and apply Mepitel One with the tacky side to the wound.
3. Remove the remaining protective film and smooth Mepitel One in place. If more than one piece of Mepitel One is required to cover the wound, overlap the edges of the dressings. If clinically indicated, more than one layer of Mepitel One can be applied.
4. When Mepitel One is used in conjunction with Avance® NPWT System, it should be changed every 48 to 72 hours, but no less than three times per week, or as instructed by the patient's clinician.*
5. Mepitel One can also be used to wrap around a piece of foam before placement into tunnelling or undermining area.

*The clinical indication for the use of Mepitel/Mepitel One with Avance NPWT System is somewhat different from the normal rationale for applying wound contact layers. This is reflected in the need to increase the frequency of dressing change over and above what is normally practiced.

Precautions and warnings

- Sharp edges or bone fragments must be eliminated from the wound area or covered by a wound contact layer (e.g. Mepitel®/Mepitel One with Safetac®)
- Always document the number of cut pieces of Mepitel/Mepitel One used in the patient's record to ensure that no Mepitel/Mepitel One is left in the wound when the dressing is changed
- Mepitel/Mepitel One is a single use dressing. Do not re-use Mepitel/Mepitel One once it has been removed from the wound as the performance of the product may deteriorate and cross-contamination may occur.

APPLYING GAUZE-BASED AVANCE NPWT SYSTEM

1. Prepare

- Prepare all dressing materials.
- Cleanse the wound bed as instructed by the clinician.
- Cleanse the periwound skin and thoroughly dry.
- Cut the film to the appropriate size allowing an overlap of 3–5 cm onto surrounding skin.



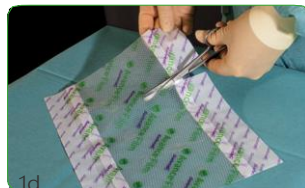
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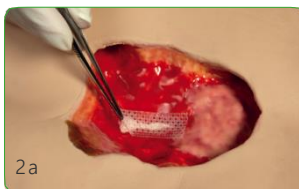


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2. Protect

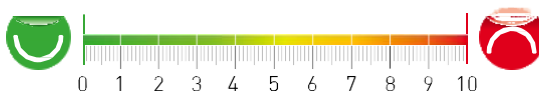
- Protect any vulnerable areas with Mepitel® or Mepitel® One.

NOTE: If any skin protection products such as pastes or lotions are used prior to film application, the adhesion level will be negatively affected.



2a

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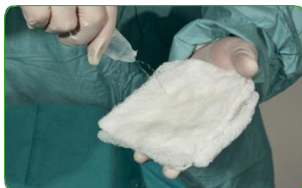


3. Apply

- Moisten the gauze with sterile water or saline.
- Place moistened gauze into the wound without overpacking.
- Remove the release liner in the middle of the film and cover the gauze allowing an overlap of 3-5cm onto surrounding skin. Remove the outer release liners.

NOTE: Do not stretch the film as it may cause loosening of the film once negative pressure is applied.

- Cut a hole in the film <2cm in diameter.
- Remove the release film on the ViewPad and use the viewing window to correctly position the ViewPad over the cut hole. Gently press onto the film.



3a



3b



3c



3d



3e

4. Commence

- Insert canister tubing into the pump and attach canister to the pump.
- Connect the ViewPad tubing to the canister tubing.
- Turn on the pump and commence therapy.
- Once the negative pressure is applied, the dressing will collapse.

NOTE: If the dressing does not collapse, the system may not be sealed. Inspect the dressing and use additional film for sealing, consider use of sealing accessories (e.g. Mepiseal®) or



4a



4b



4c



4d

remove dressing and start again.

Precautions and warnings

- Do not overlap the moistened gauze onto intact skin
- Do not pack excessive gauze into any area of the wound or use excessive force as this may damage tissue, hinder exudate removal or hinder delivery of negative pressure
- Do not place gauze into an unexplored tunnel or fistula
- The number of gauze pieces placed in the wound should be recorded in the patient's notes to ensure that nothing is left in the wound when the dressings are changed.

APPLYING FOAM-BASED AVANCE NPWT SYSTEM

1. Prepare

a. Prepare all dressing materials.

b. Cleanse the wound bed as instructed by the clinician.

NOTE: Do not use oxidising agents such as hypochlorite solutions or hydrogen peroxide prior to use of the Avance Foam dressing.

c. Cleanse the periwound skin and thoroughly dry.

d. Cut the foam, away from the wound into an appropriate size corresponding with the dimensions of the wound cavity.

NOTE: Rub the foam edges to remove any loose particles.

e. Cut the film to the appropriate size allowing an overlap of 3–5 cm onto surrounding skin.



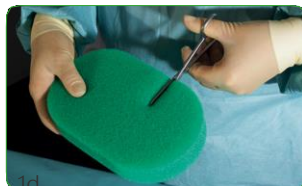
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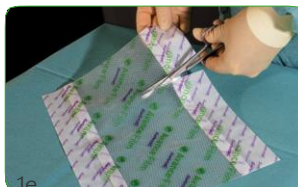
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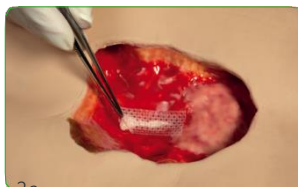


1e

2. Protect

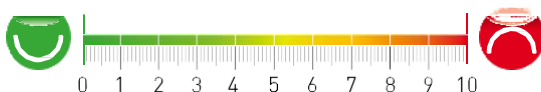
a. Protect any vulnerable areas with Mepitel® or Mepitel® One.

NOTE: If any skin protection products such as pastes or lotions are used prior to film application, the adhesion level will be negatively affected.



2a

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3. Apply

- Place the foam in the wound.
- Remove the release liner in the middle of the film and cover the foam allowing an overlap of 3-5cm onto surrounding skin. Remove the outer release liners.

NOTE: Do not stretch the film as it may cause loosening of the film once negative pressure is applied.

- Cut a hole in the film <2cm in diameter.
- Remove the release film on the ViewPad and use the viewing window to correctly position the ViewPad over the cut hole. Gently press onto the film.



4. Commence

- Insert canister tubing into the pump and attach canister to the pump.
- Connect the ViewPad tubing to the canister tubing.
- Turn on the pump and commence therapy.
- Once the negative pressure is applied, the dressing will collapse.

NOTE: If the dressing does not collapse, the system may not be sealed. Inspect the dressing

and use additional film for sealing, consider use of sealing accessories (e.g. Mepiseal®) or remove dressing and start again.



Precautions and warnings

- Do not cut the foam over the wound site, as fragments may fall into the wound
- Do not overlap the foam onto intact skin
- Do not pack excessive foam into any area of the wound or use excessive force as this may damage tissue, hinder exudate removal or hinder delivery of negative pressure
- Do not place foam into an unexplored tunnel or fistula
- The number of foam pieces placed in the wound should be recorded in the patient's notes to ensure that nothing is left in the wound when the dressings are changed.

APPLYING MEPISEAL® WITH SAFETAC® TECHNOLOGY

1. Prepare

a. Prepare all dressing materials.

b. Cleanse the wound bed as instructed by the clinician.

NOTE: Do not use oxidising agents such as hypochlorite solutions or hydrogen peroxide prior to use of the Avance Foam dressing.

c. Cleanse the periwound skin and thoroughly dry.

d. Cut the foam, away from the wound into an appropriate size corresponding with the dimensions of the wound cavity.

NOTE: Rub the foam edges to remove any loose particles.

e. Cut the film to the appropriate size allowing an overlap of 3–5 cm onto surrounding skin.



1a



1a



1b



1c



1d

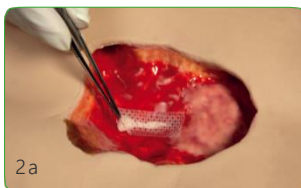


1e

2. Protect

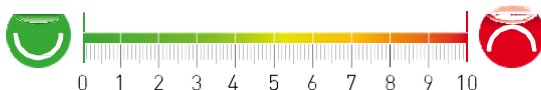
a. Protect any vulnerable areas with Mepitel® or Mepitel® One.

NOTE: If any skin protection products such as pastes or lotions are used prior to film application, the adhesion level will be negatively affected.



2a

You can reduce your patients pain by using Avance® with Safetac®



3. Apply

- a. Place the foam in the wound.
- b. To open Mepiseal, twist the green cap counter clockwise.

NOTE: Once activated, Mepiseal will remain ready for use for 5 minutes.

- c. Firmly press the plunger and apply Mepiseal to the desired area. Apply approx. 5mm from the wound edge. Do not insert Mepiseal into the wound.

NOTE: Mepiseal can also be spread over the peri-wound area using the tip of the applicator.

- d. Remove the release liner in the middle of the film and cover the foam and the Mepiseal, allowing an overlap of 3–5 cm onto surrounding skin. Remove outer release liners.

NOTE: Ensure you pat down the film in connection with the Mepiseal to ensure a seal is achieved.

NOTE: Do not stretch the film as it may cause loosening of the film once negative pressure is applied.



- e. Cut a hole in the film <2 cm in diameter.

- f. Remove the release film on the ViewPad and use the viewing window to correctly position the ViewPad over the cut hole. Gently press onto the film.

4. Commence

- a. Insert canister tubing into the pump and attach canister to the pump.
- b. Connect the ViewPad tubing to the canister tubing.
- c. Turn on the pump and commence therapy.

- d. Once the negative pressure is applied, the dressing will collapse.

NOTE: If the dressing does not collapse, the system may not be sealed. Inspect the dressing and use additional film for

sealing, consider use of sealing



4a



4b



4c



4d

accessories (e.g. Mepiseal) or
remove dressing and start again.

Frequency of change

Mepiseal® should be changed together with the Avance Transparent Film / Avance Film with Safetac technology.

Precautions and warnings

- Mepiseal must never be used for injection. For external use only
- Mepiseal is not intended as the primary fixation for life supporting devices
- If removal of the NPWT film is required within 10 minutes after application, Mepiseal can leave a residue
- Mepiseal must be used within 5 minutes after opening. Otherwise, the silicone will set in the mixer
- Mepiseal is not intended to be applied directly in the wound bed, or on the stoma
- Mepiseal is not intended as the only fixation of a wound dressing or stoma device
- Do not smooth away unset Mepiseal with gloves if they contain latex or nitrile, since those materials can affect the setting of the sealant
- Use Mepiseal with the mixer at application, as unmixed components will not set properly and product performance will be affected
- If Mepiseal is exposed to stress (e.g. mechanical forces) within 5–10 minutes of setting, it may lose its intended shape and thereby product performance may be affected
- Repositioning of Mepiseal may reduce its ability to set. If not satisfied with the positioning of Mepiseal, wait for 10 minutes before removing it and make a new application to the desired location
- If removal of the wound dressing or medical device is required within 10 minutes, Mepiseal may leave a residue which can be removed by using an adhesive remover
- Variations in skin or room temperature may affect the setting speed.

RECOMMENDED PRESSURE SETTINGS

Pressure levels

The pressure level is set according to clinician's instructions, based on the indication, the condition of the wound, the objective of the treatment and which wound dressing is being used. For general guidance, pressure settings should be:

- Foam dressings from -80mmHg to -120mmHg
- Gauze dressings from -60mmHg to -80mmHg.

Pressure may be altered according to clinical circumstances. If the patient experiences pain or discomfort, consider reducing the amount of negative pressure. Consider higher negative pressure especially in treatment of severe infections, according to the experience of the clinician^{1,2}.

Constant/intermittent settings

Generally, most wounds will have constant therapy applied to them. Intermittent therapy can be applied to promote a faster rate of granulation tissue formation, although it is not generally recommended in the following situations:

- Presence of unstable fractures
- Presence of infection
- Presence of tunnels or undermining or sinuses
- Skin grafts
- Moderate to heavy levels of exudate
- Painful wounds.

It is important to bear in mind that intermittent therapy may hinder the desired clinical outcome of NPWT. It can also be associated with negative effects such as heightened pain, sleep disturbance, and sub-optimal exudate management.

The maximum cycle setting for intermittent therapy with Avance Pump is 8 minutes on and 8 minutes off.

The on/off regime should be decided by the clinician. The condition of the wound will determine the optimal regime. Published evidence indicates that a '5 minutes on/2 minutes off' regime achieves favourable results³.

REFERENCES: 1. Timmers, M.S., et al. The effects of varying degrees of pressure delivered by negative-pressure wound therapy on skin perfusion. *Ann Plast Surg* 2005; 55(6):665-671. 2. Timmers, M.S., et al. Negative pressure wound treatment with polyvinyl alcohol foam and polyhexanide antiseptic solution instillation in post-traumatic osteomyelitis. *Wound Repair Regen* 2009; 17(2):278-286. 3. Morykwas, M.J., et al. Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. *Ann*

DRESSING CHANGES AND REMOVAL

Frequency

Dressings should be changed every 48 to 72 hours, but no less than three times per week, or according to the clinician's instructions. The frequency of dressing changes should be based on an evaluation of the wound condition (e.g. wound infection) rather than standard recommendations.

Dressing removal procedure

- Turn off the Avance Pump
- Allow the dressing in the wound to rise, indicating that no negative pressure is present in the wound
- Remove the film dressing. If using Avance Transparent Film, gently peel back one corner of the film dressing and stretch the dressing to facilitate breakage of the seal. Proceed with this technique until the film is completely removed
- Gently remove gauze or foam and wound contact layer (if used), along with the drain or ViewPad, from the wound surface
- Disconnect the drain or ViewPad from the canister tubing
- Discard all soiled disposable equipment in accordance with local guidelines/regulations.

If the patient experiences pain, as a consequence of dressing adhering to underlying tissue, then moisten the dressing with generous amounts of saline or tap water (depending on local wound care protocols). Consider the use of a wound contact layer, e.g. Mepitel® with Safetac®, at next dressing change to minimise pain and trauma.

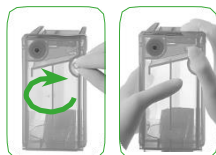
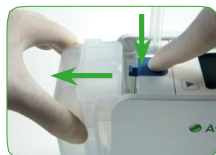
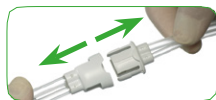
Precautions and warnings

The clinician must ensure that careful records are kept of the type and number of dressings used at each re-application of the Avance NPWT System. Retained dressing materials could cause significant health issues. It is the responsibility of the clinician to ensure that all dressing material is removed at each dressing change.

CHANGING THE CANISTER AND TUBING

Change Avance Canister and Avance Tubing, when the canister is full, by visual inspection or when alarm sounds, in accordance with instructions on the pump display or minimum once a week.

1. Provide sterile canister and sterile tubing.
2. Clamp canister tubing.
3. Press the "Standby" button [▶ > 3 sec.] and the pressure will be turned OFF.
4. Disconnect the canister tubing from the tubing connected to the dressing.
5. Release and remove canister.



6. Seal used canister with cap.



7. Remove canister tubing in direction of the arrow.



8. Unpack new canister tubing and connect to Avance® Pump. Insert the tubing base into the pump (straight push).



9. Unpack new canister, position and click into Avance Pump.

10. Connect the canister tubing to the tubing connected to the dressing. Ensure that the canister tubing is un-clamped.



11. Press "On" with [▶]. Pressure is built up.

12. Dispose canister and canister tubing in accordance with local procedures. In the home care settings, return disposables to care giver for correct disposal - Must not be disposed together with household refuse.

WOUND ODOUR AND INFECTION

All wounds are colonised with bacteria, many of which have little or no effect on wound healing outcomes. Some bacteria are the source of wound odour, which is common when occlusive and semi-occlusive methods of wound dressings are used. Cleansing the wound bed in line with local wound protocols may help control wound odour. However, the clinician must be vigilant for the signs of wound infection.

Clinicians may decide to use NPWT for infected wounds in conjunction with standard treatment for infection. It may also be possible to continue NPWT if a wound becomes infected during treatment. The frequency of dressing changes may need to be increased if infection is present, due to an increase in exudate levels during the infective episode.

For further guidance on recognising the signs of infection, please consult Principles of Best Practice. A World Union of Wound Healing Societies Initiative. Wound infection

SPECIALIST APPLICATION TECHNIQUES

SUTURES/STAPLES

Sutures and staples should be covered with a non-adherent dressing (e.g. Mepitel®/Mepitel One with Safetac®) prior to application of the Avance NPWT System. This will prevent them from becoming snagged or entangled in the gauze/foam during therapy and dressing removal.

TUNNELLING

Due to the diverse nature of wound development, it is not unusual for wounds to form tracks and tunnels. If untreated, these tracks can form pockets within the wound in which debris can become trapped and bacteria can multiply, providing an environment for prolonged inflammation, infection, abscess formation and wound chronicity¹. The clinician should aim to facilitate healing of these wounds from the base up. The Avance NPWT System can be used to achieve this goal. The tunnel area requires to be assessed and dressed appropriately before the remaining wound can be dressed.

Due to the technical issues in applying and removing dressings in wounds with tunnels, most clinicians prefer to use a gauze-based technique. However a foam dressing can be applied.

Procedure with AMD Gauze and Avance Round Drain

Therapeutic delivery setting: Constant negative pressure.

Negative pressure setting: -60mmHg to -80mmHg when using Gauze, or as directed by clinician. Follow all local procedures for cleaning and preparing the wound bed for a dressing application.

1. Measure the area/length of the tunnel to be treated and record this.
2. Select the Avance Round Drain.
3. Cut the white part of the round drain to the measurement of the tunnel plus enough additional length so that the open channels of the drain extend from the centre of the wound into the distal end of the tunnel.
4. Gently insert the drain into the tunnel and feed it through until it reaches the distal

section of the tunnel; then pull it back by approximately 1 cm, leaving the distal end of the tunnel clear.

5. For some tunnelling areas it may be necessary to wrap moistened gauze around the drain. Moisten the gauze with sterile water or sterile saline solution. Wrap this around the drain as required and insert into the tunnel area.
6. Dress the remaining wound area: moisten the gauze dressing and apply this into the wound area. Work the gauze around the remaining tubing of the round drain.
7. Continue to fill the cavity with moistened gauze. Loosely fill the wound to skin level with additional moist gauze.
8. Cut the film to the appropriate size, allowing about a 3 to 5 cm margin on the peri-wound skin.
9. Gently apply the film over the gauze dressing, round drain tubing and surrounding skin.
10. When approaching the round drain tubing with the film, lift the drain up and pinch the film around the drain to create an airtight seal.
11. Connect tubing to the Avance Pump and apply negative pressure. Ensure that the dressing collapses and a seal is achieved.

The above steps should be completed for each subsequent dressing change until the tunnel closes.

REFERENCES: 1. World Union of Wound Healing Societies. Principles of Best Practice. A World Union of Wound Healing Societies Initiative. Wound infection in clinical practice. An international consensus. London: MEP Ltd, 2008.

Precautions and warnings

- The Avance NPWT System should not be used to treat unexplored tunnels

Procedure with Avance Foam and Avance Round Drain

Therapeutic delivery setting: Constant negative pressure.

Negative pressure setting: -80mmHg up to -120mmHg when using Avance Foam, or as directed by clinician.

There are a number of options to consider here. The round drain might be inserted into the tunnel area and Avance Foam used in the remaining wound area. Alternatively a piece of foam and the round drain may be inserted into the tunnel area and foam in the remaining wound area.

If the foam is used with the round drain, care must be taken to ensure that the foam does not adhere within the tunnel area. The use of a wound contact layer (e.g. Mepitel®/Mepitel

One with Safetac®) should be strongly considered in this instance.

Follow all local procedures for cleaning and preparing the wound bed for a dressing application.

1. Measure the length of the tunnel to be treated and record this.
2. Select the round drain.
3. Cut the round drain to the measurement of the tunnel plus enough additional length so that the open channels of the drain extend from the centre of the wound into the distal end of the tunnel.
4. Gently insert the drain into the tunnel and feed it through until it reaches the distal section of the tunnel; then pull it back by approximately 1 cm, leaving the distal end of the tunnel clear.

If using Avance Foam and Avance Round Drain for the tunnelling area.

- Cut a section of foam to the measurement of the tunnel plus an additional 3 to 4 cm.
- Make an incision in the foam to enable the drain to be inserted, ensuring that the drain is at least 1cm from the distal end. Take a piece of Mepitel®/Mepitel One and wrap this around the piece of foam
- Gently insert the drain and foam into the tunnel and feed it through until it reaches the distal section of the tunnel; then pull it back by approximately 1cm, leaving the distal end of the tunnel clear.

5. Fill the wound area with foam to the level of the skin. Ensure that the piece of foam in the tunnel is in contact with the foam in the wound area. Do not pack the foam into the wound area.
6. Make an incision in the foam. Place the foam gently in the wound cavity. Position the round drain within the incision.
7. Cut the film to an appropriate size, allowing an overlap of 3–5 cm onto the peri-wound area.
8. Cover the wound and the drain with film. Do not stretch the film.
9. Pinch the film around the drain to create an airtight seal. If an airtight seal is not achieved, use additional film for sealing. Consider using sealing accessories (e.g. Mepiseal®) or remove dressing and start again.
10. Connect the drain to the canister tubing. Attach the canister to the pump. Turn on the pump. Ensure that the dressing collapses and a seal is achieved.

The above steps should be completed for each subsequent dressing change until the tunnel closes.

Precautions and warnings

- Ensure that the cut foam is at least 2 cm x 2 cm in area. If the foam is cut into a smaller section, there is a risk of breakage and retention in the wound
- The Avance NPWT System should not be used to treat unexplored tunnels.

• UNDERMINING

Where a void exists beneath the edge of the wound margin, it is important to facilitate drainage and tissue granulation of this area. Some areas of undermining will vary in size and will require to be fully examined before application of NPWT. It is the responsibility of the patient's clinician to decide on whether to use Avance Foam or AMD Gauze within this area. The use of gauze may reduce pain at dressing changes in susceptible patients¹.

Depending on the size of the undermining area, the Avance Round Drain can be inserted into this area with or without moistened gauze. Alternatively, moistened gauze can be inserted into the area of undermining with or without a round drain. If Avance Foam is used with the Avance Round Drain, care must be taken to ensure that the foam does not adhere within the undermining area. The use of a wound contact layer (e.g. Mepitel®/Mepitel One with Safetac®) should be strongly considered in this instance.

Procedure with Gauze

Therapeutic delivery setting: Constant negative pressure.

Negative pressure setting: -60mmHg to -80mmHg, when using Gauze, or as directed by clinician.

Follow all local procedures for cleaning and preparing the wound bed for a dressing application.

Technique with AMD Gauze and Avance Round Drain

1. Measure and record the undermined area to be treated.

2. Select the round drain.
3. Cut the drain to twice the measurement of the undermined area plus enough additional length for the drain to extend to the centre of the wound.
4. Coil the drain until it fills the undermined area and extends to the centre of the wound.
5. Moisten the gauze and apply into the rest of the wound area. Fill the wound cavity with moistened gauze to the level of the skin.
6. Position the round drain within the gauze, this should ideally come out of the wound area at the edge of the wound.
7. Cut the film to the appropriate size allowing a 3 to 4 cm margin on the skin.
8. Gently apply the film over the wound dressing, drain and surrounding skin.
9. Lift the drain and pinch the film around the drain to create an airtight seal. Cover the wound area with the film.
10. Connect tubing to the Avance Pump and apply negative pressure. Ensure that the dressing collapses and a seal is achieved.

The above steps should be completed for each subsequent dressing change until the undermined area closes.

Technique with Avance Flat Drain

1. Measure and record the undermined area to be treated.
2. Moisten the gauze and insert this into the undermined area. Do not pack this into the area.
3. Ensure that this gauze is visible in the wound area and that a piece of the gauze is in contact with the rest of the gauze in the wound cavity.
4. Measure the length of the wound and cut the flat drain approximately 1 to 2 cm shorter than the measured distance of the wound.
5. Wrap a piece of moistened gauze around the flat drain.
6. Place the drain and gauze into the wound cavity. Loosely fill the wound to skin level with additional fluffed moist gauze.
7. Cut the film to the appropriate size allowing a 3 to 5 cm margin on the skin.
8. Gently apply the film over the wound dressing, drain and surrounding skin.
9. Lift the drain and pinch the film around the drain to create an airtight seal.
10. Connect tubing to the Avance Pump and apply negative pressure. Ensure that the dressing collapses and a seal is achieved.
11. The above steps should be completed for each subsequent dressing change until the undermined area closes.

Procedure with Avance Foam

Therapeutic delivery setting: Constant negative pressure.

Negative pressure setting: -80mmHg to -120mmHg, when using Avance Foam, or as directed by clinician.

Technique with Avance Round Drain

1. Measure and record the undermined area to be treated.
2. Select the round drain.
3. Cut the drain to ensure it is long enough to maintain adequate contact with the undermined area and the foam dressing.
4. Trim the foam to the size of the measured undermined area.
5. Apply the wound contact layer (e.g. Mepitel®/Mepitel One) around the foam before inserting this into the undermined area. The contact layer will prevent in-growth of tissue into the foam and allow for an easier insertion and removal of the foam from the undermining area.
6. Insert the drain and foam into the undermined area, ensure that the drain is positioned comfortably in this area.
7. Fill the rest of the wound area with foam ensuring that this is in contact with the foam inserted in the undermining area.
8. Position the drain within the foam, this should ideally come out of the wound area at the edge of the wound.
9. Cover the wound area with the film. Incorporate the drain and lift the drain and pinch the film around this to create a seal.
10. Connect tubing to the Avance Pump and apply negative pressure. Ensure that the dressing collapses and a seal is achieved.
11. The above steps should be completed for each subsequent dressing change until the undermined area closes.

Technique with Avance ViewPad 2

1. Measure and record the undermined area to be treated.
2. Trim the foam to the size of the measured undermined area.
3. Apply the wound contact layer (e.g. Mepitel®/Mepitel One) around the foam before inserting this into the undermined area. The contact layer will prevent in-growth of tissue into the foam and allow for an easier insertion and removal of the foam from the undermining area.
4. Gently pull back about 1cm. Ensure that this piece of foam connects to the rest of the foam in the wound cavity area.
5. Fill the rest of the wound with foam ensuring that this is in contact with the foam inserted in the undermining area.
6. Cover the wound area and the foam dressing with film.
7. Cut a 1cm x 1cm hole in the film and then apply the transfer pad.
8. Connect tubing to the Avance Pump and apply negative pressure. Ensure that the dressing collapses and a seal is achieved.
9. The above steps should be completed for each subsequent dressing change until the undermined area closes.

BRIDGING TECHNIQUE USING AVANCE FOAM AND AVANCEVIEWPAD ™

1. Prepare

- a. Prepare all dressing materials.

- b. Cleanse the wound bed as instructed by the clinician.

Cleanse the peri-wound skin and thoroughly dry.

NOTE: Do not use oxidising agents such as hypochlorite solutions or hydrogen peroxide prior to use of the Avance Foam dressing.

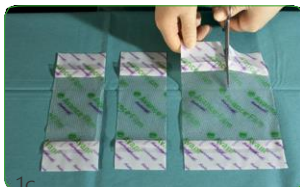
- c. Identify a relocation site for the ViewPad. Cut the film into appropriate size and shape, to protect the skin underneath and the "bridge" section between the wound and the relocation site.



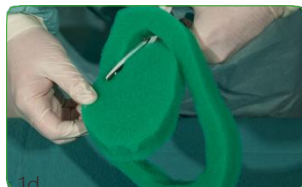
1a



1b



1c



1d

- d. Cut the foam, away from the wound into appropriate size corresponding with the dimensions of the wound cavity. Cut the foam for the bridge section into strips or cut around the foam to create one long strip. Cut a piece of foam big enough to support the ViewPad at the location site.

NOTE: Rub the foam edges to remove any loose particles.

2. Protect

If needed, protect any vulnerable areas with Mepitel® or Mepitel® One.

- a. Dry the skin thoroughly.
Place the film strips onto the skin from the wound edge to the relocation site.

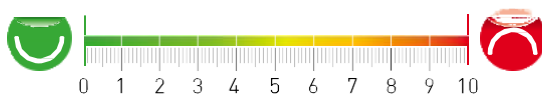
NOTE: If any skin protection products such as pastes or lotions are used prior to film application, the adhesion level will be negatively affected.



2a



You can reduce your patients pain by using Avance® with Safetac®



3. Apply

- a. Place the foam strip on top of the protective film bridge, from the wound to the relocation site and begin to secure in place. Ensure foam-to-foam contact throughout. Place the foam in the wound.



- b. Remove the release liner in the middle of the film and cover the foam allowing an overlap of 3-5cm onto surrounding skin. Remove the outer release liners. Ensure that all foam is covered to create a seal.



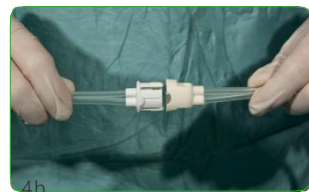
NOTE: Do not stretch the film as it may cause loosening of the film once negative pressure is applied.

- c. Cut a hole in the film, <2 cm in diameter, at the relocation site.

- d. Remove the release film on the ViewPad and use the viewing window to correctly position the ViewPad over the cut hole. Gently press onto the film.

4. Commence

- a. Insert canister tubing into the pump and attach canister to the pump.



- b. Connect the ViewPad tubing to the canister tubing.

- c. Turn on the pump and commence therapy.

- d. Once the negative pressure is applied, the dressing will collapse.

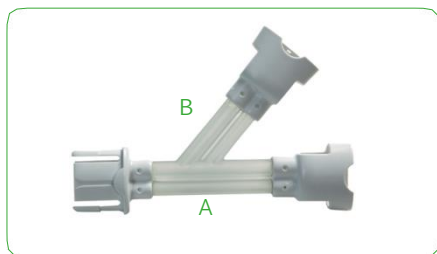
NOTE: If the dressing does not collapse, the system may not be sealed. Inspect the dressing

and use additional film for sealing, consider use of sealing accessories (e.g. Mepiseal®) or remove dressing and start again.



USING Y-CONNECTORS

In certain circumstances, it may be possible to use one Avance Pump to apply NPWT to more than one wound on the same patient. In such cases, an Y-connector can be used to connect each wound drain to the canister tubing. When two View Pads are used, only the View Pad connected to the straight arm of the Y-connector (A) is flushed with air. A blockage in the View Pad connected to the curved arm (B) will not be detected by the unit. Only one Y-connector should be used for each pump unit.



1. Connect the ViewPad and/or the drain adaptor to the Y-connector.



2. Connect the Y-connector to the canister tubing.



ORTHOPAEDIC DEVICES/EXTERNAL FIXATORS

The presence of orthopaedic devices in the wound such as pins, rods or plates is not a contraindication for use with the Avance NPWT System. NPWT has been used to form granulation tissue in these types of wounds. However, some minor adaptations to the dressing technique will be required.

Consider applying either Avance Foam or Gauze to the wound. Each pin site that is present in the wound will need to be sealed. This can be achieved with a number of methods. The use of Mepiseal® with Safetac® around the fixators can assist with achieving and maintaining a seal. Foam should be applied into the wound area. Treat each fixator individually. Consider the use of Mepitel®/Mepitel One around each fixator. This should be rolled and wrapped around the fixator and then the foam applied around this. The film should be cut and applied around the fixator using a sandwich technique.

Mepiseal can be applied around the fixator above the foam. Then the film should be cut and applied around the fixator in a sandwich technique.

If using moistened gauze in the wound, the pin site/s will need to be dried before applying the film and any Mepiseal.

It may be necessary to incorporate the fixator into the film in order to achieve a seal.

SPECIALISED WOUND TYPE APPLICATIONS

NPWT can be used with wounds that present the clinician with specific clinical challenges that cannot be overcome by routine therapies. This section identifies such wound types and explains how the Avance NPWT System can be used to address these challenges.

SKIN GRAFTS

The Avance NPWT System is indicated for the management of skin grafts. Grafting is undertaken to restore the integrity and function of the skin, re-establish a barrier to infection, achieve optimum cosmetic appearance and preserve joint mobility. Skin grafting is performed to promote healing of:

- Deep dermal and full thickness burns
- Venous leg ulcers
- Pressure ulcers
- Diabetic foot ulcers
- Areas of full thickness skin loss, following trauma
- Post-operative skin defects.

NPWT has been used successfully on different types of skin grafts:

- Split-thickness skin grafts
- Full-thickness skin grafts
- Meshed grafts
- Composite grafts
- Cultured and manufactured skin substitutes.¹

Role of NPWT in graft management

- The attributes of NPWT (exudate management, moisture control, improved blood flow, and wound stabilisation) suggest it is a useful method of maximising the probability of successful graft take. It can assist with a rapid revascularisation of the newly applied graft²
- The Avance NPWT System acts as an effective barrier to bacterial ingress to the wound while the continued removal of exudate and debris helps to reduce the risk of infection.^{3,4}

Objectives of NPWT in skin grafting

- Provide support and stability for skin grafts (split-thickness and full-thickness), thereby holding the graft in place
- Help protect the wound environment e.g. minimise shearing forces
- Remove fluid and keep the grafted area free from excess moisture
- Assist skin or bio-engineered tissue graft take.

Wound bed preparation (pre-graft)

- The Avance NPWT System can be utilised during preparation of the wound bed to provide an optimal healing environment (increased vascularisation, production of a granular wound bed, management of exudate and wound oedema)
- The clinician should decide the wound dressing and pressure settings according to the clinical presentation.

Application of NPWT

- Apply Avance NPWT System to stabilise the wound and ensure secure fixation of the graft to the wound bed
- As the main objective of using NPWT for graft management is not granulation tissue formation, a lower negative pressure setting is suggested. The setting will be determined by wound size, amount of exudate and dressing type
- Optimal time for application is directly after graft placement
- Ideally, the wound should be left undisturbed for 5–7 days
- NPWT should be discontinued once the graft has revascularised
- Continued use of NPWT will not promote graft uptake if the graft itself is no longer viable.

REFERENCES: 1. Gupta, S. Optimal use of negative pressure wound therapy for skin grafts. *Int Wound J* 2012;9(Suppl 1):40-47. 2. Clare, M.P., et al. Experience with the vacuum assisted closure negative pressure technique in the treatment of non-healing diabetic and dysvascular wounds. *Foot Ankle Int* 2002;23(10):896-901. 3. Domingos Hadamitzky, C., et al. Vacuum assisted wound closure in postoperative periprosthetic groin infections: a new gold standard? *J Cardiovasc Surg (Torino)* 2007;48(4):477-483. 4. Chen, Y., et al.

Managing deep sternal wound infections with vacuum-assisted closure. ANZ J Surg 2008;78(5):333-336.

Procedure with AMD Gauze and Avance ViewPad

1. Check for sutures holding the graft in place.
2. Apply a wound contact layer (e.g. Mepitel®/Mepitel One with Safetac®) directly over the graft and beyond the suture line (if present) by about 1cm.
3. Place moistened gauze to cover the wound contact layer then place some dry gauze over this.
4. Cover the wound area with film.
5. Cut a hole in the film at least 1cm by 1cm.
6. Apply the ViewPad over the cut hole.
7. Connect the tubing to the canister tubing.
8. Turn on the pump. Ensure 'constant therapy' is selected and a pressure setting between -60mmHg and -80mmHg. (Commence at lower end of range and adjust as required.)
9. Discontinue NPWT if exudate levels and appearance are indicative of possible wound infection; or if fresh frank blood is present in the tubing.

Procedure with Avance Foam and Avance ViewPad

1. Check for sutures holding the graft in place.
2. Apply a wound contact layer (e.g. Mepitel/Mepitel One) directly over the graft and beyond the suture line (if present) by about 1 cm.
3. Cut the foam to the same size as the wound contact layer and apply.
4. Cover the foam and peri-wound area with film.
5. Cut a hole 1cm by 1cm in the film.
6. Apply the ViewPad to the film.
7. Turn on the pump. Ensure 'constant therapy' is selected and a pressure setting between -80mmHg and -120mmHg. (Commence at lower end of range and adjust as required.)
8. Discontinue NPWT if exudate levels and appearance are indicative of possible wound infection; or if fresh frank blood is present in the tubing.

DEHISCED SURGICAL WOUNDS

The Avance NPWT System is indicated for the management of wound breakdown following surgical procedures. The breakdown of surgical wounds is primarily due to wound infection, but can also result from other factors such as excessive tension on the wound edges, haematoma formation, compartment syndrome and tissue necrosis¹.

Management of these wounds involves the treatment of any underlying cause, debridement of non-viable tissue, stabilisation of the wound, initiation of appropriate antibiotics as required, and preparation of the wound bed, either for secondary surgical closure or healing by secondary intention. The use of the Avance NPWT System is recommended early in the management of surgical wound breakdown.

Objectives of NPWT in management of the dehisced surgical wound

- Stabilisation of the wound, facilitating patient movement and comfort
- Prevention of wound retraction
- Promotion of wound contraction
- Provision of a closed, moist wound-healing environment
- Promotion of wound bed perfusion
- Elimination/removal of fluid, exudate and infectious materials
- Acceleration of granulation tissue formation
- Reduction of oedema.

Treatment options:

The dehisced surgical wound may be treated with either foam or gauze-based dressings in conjunction the Avance NPWT System.

- When using foam-based dressings, initiate the Avance NPWT System at setting parameters from -80mmHg to -120mmHg constant negative pressure or as directed by the clinician
- When using gauze-based dressings, initiate the Avance NPWT System at setting parameters from -60mmHg to -80mmHg constant negative pressure or as directed by the clinician
- Always consider the anatomical structures present in the wound and, if necessary, use a wound contact layer (e.g. Mepitel®/Mepitel One with Safetac®) to help provide protection
- Dressings should be changed every 48–72 hours, but not less than three times per week, for non-infected wounds; however, infected wounds may require more frequent changes.

Precautions and warnings

-
- Consider using multiple wound contact layers (e.g. Mepitel/Mepitel One) over exposed structures such as organs, blood vessels or recent anastomosis.

REFERENCE: 1. Milne, J., et al. Post-operative incision management made easy. Wounds UK 2012;8(4 Suppl):1-4

STERNAL WOUNDS

The management of sternal wounds poses specific challenges, i.e.

- Instability of the chest wall can seriously affect respiratory function
- Infection of the sternal cartilage is difficult to manage
- The presence of vital organs immediately under (or within) the wound margins.

Objectives of NPWT in management of sternal wounds

- Stabilisation of the wound, facilitating optimum respiratory function, patient mobility and comfort
- Promotion of wound contraction
- Provision of a closed, moist wound-healing environment
- Promotion of wound bed perfusion
- Elimination/removal of fluid, exudate and infectious materials
- Acceleration of granulation tissue formation.

Special considerations

- In wounds where the sternum is intact and stable, with no evidence of bone infection (superficial sternal wounds), management should follow the same lines as for dehiscent wounds. Secondary surgical wound closure is rarely attempted and the wound is generally allowed to heal by secondary intention
- In subjects with an unstable sternum, deep sternal wound infection or mediastinitis, careful assessment of the wound bed is vital to identify if underlying structures such as the pericardium are present in the lower margins of the wound
- If the patient has mediastinitis, certain issues need consideration: sternal wires may be required to be removed, debridement of bone may be required prior to placement of NPWT; and systemic antibiotics may also be required. A specialised cardiothoracic clinician should be involved with the assessment and application of the dressing
- The use of the Avance NPWT System should not be applied directly onto any underlying

organs. If NPWT is considered appropriate by the patient's lead surgeon, underlying structures must be protected by adequate wound contact layers (e.g. Mepitel®/Mepitel One with Safetac®) under the gauze or foam dressing

- The use of the Avance NPWT System must be monitored closely, particularly in patients with unstable sternal wounds
- The Avance NPWT System should be set to deliver constant negative pressure throughout treatment to assist in stabilisation of the chest wall
- During the first application, patient tolerance to the effects of NPWT should be closely monitored and pressure levels adjusted accordingly
- The constant application of pressure causes wound edges to pull together, providing a 'splinting' effect, which imparts mobility and comfort to the patient
- Dressing changes should be undertaken every 48–72 hours, but not less than three times per week, for non-infected wounds, but more frequently if deemed necessary by the treating clinician.

Precautions and warnings

- Consider using multiple wound contact layers (e.g. Mepitel®/Mepitel One) over exposed structures such as organs, blood vessels or recent anastomosis.

Please consult your local Mölnlycke Health Care representative for specific application techniques.

OPEN ABDOMEN WOUNDS

A number of surgical emergencies, including peritonitis, intra-abdominal trauma and mesenteric ischaemia, can result in wounds that cannot be completely closed by traditional techniques. 'Open abdomen' is defined as the inability to close the abdominal fascia after laparotomy. Situations where open abdomens may occur include:

- In the operating theatre the surgeon may be unable to close the patient's wound due to oedema
- The surgeon closes the wound but there is subsequent dehiscence of the wound
- There is a need for the surgeon to undertake further surgical procedures and it is deemed preferable to delay closure of the wound until a later time
- The patient displays signs or is assessed at risk of developing intra-abdominal hypertension and/or abdominal compartment syndrome
- In the presence of infection and to allow for open drainage.

In some cases, the surgeon must leave the wound open until surgical closure is possible. In other cases, wounds may be managed and allowed to close by secondary intention. This may take many months to occur. Open abdomen wounds are classified as superficial, deep, or complex.

In wounds where the abdominal muscle and fascia remains intact, the wound is classified as 'superficial' and can be treated as outlined in an earlier section of these guidelines for treating dehiscent surgical wounds.

If deeper structures such as muscle and fascia are visible in the wound, the wound is described as 'deep'. Deep abdominal wounds may also be treated as outlined in an earlier section of these guidelines for treating dehiscent wounds; however, care must be taken to avoid trauma to the fascia, which could result in the formation of fistulas. For any exposed fascia, the use of a wound contact layer (e.g. Mepitel®/Mepitel One with Safetac®) may be considered to minimise adhesion and damage.

Where the fascia is not intact and organs are exposed in the abdominal cavity, the wound is referred to as 'complex'. In these cases, patients are often managed using a damage control approach; the wound is kept open to allow subsequent re-exploration or to prevent elevated intra-abdominal pressure.

The Avance Foam Abdominal Dressing Kit is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries may be required. Its intended use is for patients who have open abdominal wounds with exposed viscera and organs and including, but not limited to, patients with abdominal compartment syndrome.

For further details see the instructions for use for the Avance Foam abdominal dressing.

Please consult your local Mölnlycke Health Care representative for detailed information about Avance Foam Abdominal Dressing Kit.

Special considerations

- Superficial abdominal wounds should be treated as described in the 'Dehisced surgical wounds' section
- When using Avance Foam, consider negative pressure settings of -80mmHg to -120mmHg
- When using AMD Gauze, consider negative pressure settings of -60mmHg to -80mmHg Ensure that the flat drain does not come into contact with exposed organs or vessels
- The clinician must carefully monitor the patient and wound progress. If there are changes in exudate volume or type (particularly if faecal matter is present), the clinician/surgeon must be immediately informed and the wound must be reassessed.

Precautions and warnings

- Consider the use of multiple wound contact layers (e.g. Mepitel®/Mepitel One) over exposed structures such as organs, blood vessels or recent anastomosis
- Management of the complex open abdominal wound is a highly specialised skill and requires a multi-disciplinary approach to care. NPWT has been found to be beneficial in the management of these wounds; however, successful use of this technique requires specially designed dressings (e.g. Avance Foam Abdominal Dressing Kit) and a high level of technical skill and experience.

Please contact your local Mölnlycke Health Care representative for specific application techniques

ACUTE WOUNDS

Generally, acute (traumatic) wounds are surgically closed with sutures, staples or tissue adhesives at, or soon after, injury. However, in some cases, acute wounds can show wound characteristics which prevent their primary closure; wounds may be contaminated with debris, carry a high bacterial load or there may be poor wound bed vascularity. In such cases, delayed closure or healing by secondary intention may be indicated. The challenge in such circumstances is to control and manage wound exudate, bacterial burden and provide an optimal, moist wound-healing environment in which vascularised granulation tissue can develop.

Objectives of NPWT in management of acute wounds

- Promotion of granulation tissue formation
- Promotion of perfusion
- Maintenance of a closed-wound environment
- Removal of oedema
- Removal of exudate and minimising bacterial colonisation
- Assistance with wound contraction and closure.

Treatment options

- Therapeutic delivery setting should be set at constant negative therapy
- When using AMD Gauze, consider negative pressure settings between -60mmHg to -80mmHg and between -80mmHg and -120mmHg when using Avance Foam, unless otherwise directed by the clinician
- Dressing changes should be undertaken approximately every 48–72 hours, but not less than three times per week, for non-infected wounds, but may have to be undertaken more frequently if infected.

Special considerations

- It is imperative that tendons, ligaments, blood vessels, organs and nerves are totally covered and protected with a wound contact layer such as Mepitel®/Mepitel One with Safetac® before applying the Avance NPWT System
- When using the Avance NPWT System, consider the use of single or multiple wound contact layers (e.g. Mepitel/Mepitel One), dependent on the structure that requires protection

- Acute wounds with exposed bone or fractures can benefit from the use of the Avance NPWT System by managing exudate, promoting wound granulation and controlling bacterial bioburden. All fractures should be stabilised before application of NPWT. Sharp edges or bone fragments must be eliminated from the wound area or covered by a wound contact layer
(e.g. Mepitel/Mepitel One).

Precautions and warnings

- Consider the use of multiple wound contact layers (e.g. Mepitel/Mepitel One) over exposed structures such as organs, blood vessels or recent anastomosis.

HARD-TO-HEAL (CHRONIC) WOUNDS

Wounds can become chronic and hard-to-heal for a number of systemic and local reasons. Poor vascularisation, the presence of wound oedema, high levels of bioburden and the presence of high levels of pro-inflammatory cytokines and metalloproteases have all been indicated to have a negative impact on wound healing¹. NPWT has been demonstrated to have a positive effect on wounds which have become static by modulating the local wound environment. It is important to have a clear objective when using NPWT with a chronic wound type. This should be reviewed on a regular basis. A fair assessment of the progress of the wound would be after a two-week period. Some changes should have occurred within this period. If nothing has changed, ensure that all other patient factors have been addressed – for example, nutrition, hydration and positioning.

Objectives of NPWT in management of hard-to-heal (chronic) wounds

- Assistance in the formation of granulation tissue
- Removal of oedema and exudate
- Promotion of perfusion
- Assistance in wound contraction and closure
- Provision of a closed, moist wound healing environment.

Special considerations

- Pressure settings for AMD Gauze should be -60mmHg to -80mmHg and -80mmHg to -120mmHg for Avance Foam, unless otherwise directed by the clinician
- Negative pressure should be delivered in the 'constant' mode for the first 48–72 hours; depending on the treatment goal for NPWT, consider changing to 'intermittent' mode if the local wound condition permits
- Dressing changes should be undertaken approximately every 48–72 hours, but not less than three times per week, for non-infected wounds, but may have to be undertaken more frequently if infected
- The wound should be regularly assessed for progress towards the desired objective. Once the objective has been met, then NPWT should be discontinued.

REFERENCES: 1. European Wound Management Association, (EWMA). Position Document. Management of wound infection. London: MEP Ltd, 2006.

PRESSURE ULCERS

Pressure ulcers are frequently found to be chronic in nature and may take many months to heal. Stage/Category I and II pressure ulcers normally heal with the initiation of pressure relief, maintenance of good nutritional standards and the use of appropriate wound treatment protocols. These types of pressure ulcer are therefore *not* suitable for treatment with NPWT.

In the treatment of Stage/Category III and IV ulcers (full-thickness pressure ulcers), the Avance NPWT System can be successfully employed as a definitive treatment or as a means of optimising the wound bed, aiding in the promotion of granulation tissue formation.¹

Objectives of NPWT in management of pressure ulcers:

- Assistance in the formation of granulation tissue
- Removal of oedema and exudate
- Promotion of perfusion
- Assistance in wound contraction and closure
- Provision of a closed, moist wound-healing environment
- Preparation of the wound bed prior to possible surgical intervention such as a rotational flap, free flap or skin grafting.

Special considerations

- Care must be taken to ensure that the placement of the drain, ViewPad and drainage tube does not increase the risk of further tissue damage. Many pressure ulcers develop over bony prominences and so it may be advisable to use a bridging technique to move the tubing away from high-risk structures/areas
- In deep (Stage/Category IV) pressure ulcers, bone may be visible in the wound. This should be covered with a wound contact layer (e.g. Mepitel®/Mepitel One with Safetac®) prior to application of the foam or gauze dressing
- Any tunnelling or undermining should be managed, as described in an earlier section of these guidelines
- Negative pressure settings should be set at between -60mmHg and -80mmHg for AMD Gauze and up to -120mmHg for Avance Foam. However, the pressure setting used should be determined and adjusted, as appropriate, by the clinician
- Dressing changes should be undertaken approximately every 48–72 hours, but not less than three times per week, for non-infected wounds, but may have to be undertaken more frequently if infected.

DIABETIC FOOT ULCERS (DFUs)

Ulceration of the foot in the patient with diabetes is a major cause for non-traumatic limb amputation, with 100 diabetic-related amputations occurring every week in the UK¹. Management of the DFU is centred on a multidisciplinary approach for the prevention of ulceration and care; however, ulceration remains an all-too-frequent complication. Deeper ulcers are associated with a higher incidence of osteomyelitis and chronic non-healing. Superficial ulceration (Wagner Classification System for Diabetic Foot Ulcers, and the University of Texas (UT) Diabetic Foot Classification System Grade 0 and I ulcers) responds to standard methods of debridement, wound management and off-loading.

However, in the treatment of Stage II–V (Wagner scale) and II–III (UT scale) ulcers, the Avance NPWT System can be used as a definitive treatment.

For further guidance on the use of NPWT in the treatment of DFUs, please refer to the TUSCON guidelines (see box below)².

TUSCON guidelines

These guidelines suggest that NPWT be deployed in:

- Larger ulcers
- Deeper ulcers
- Post-surgical debridement
- Partial foot amputation
- NPWT should be continued until there is a healthy granular wound bed. NPWT should not be applied to any wound prior to debridement.
- Wounds that are small and responding to conventional treatment are not suitable for NPWT
- NPWT can be applied after re-vascularisation, providing there are no signs to suggest residual infection
- NPWT is not a treatment for osteomyelitis but can be used following 24 hours of observation after surgical excision and drainage
- NPWT can be used on plantar wounds, providing adequate removable off-loading is used.

REFERENCES: 1. National Diabetes Support Team. Diabetic Foot Guide. 2006. www.diabetes.nhs.uk/downloads/NDST_Diabetic_Foot_Guide.pdf 2. Andros, G., et al. Consensus statement on negative pressure wound therapy for the management of diabetic foot wounds. Wounds 2006 (Suppl)

Objectives of NPWT in management of diabetic foot wounds

- Assistance in the formation of granulation tissue
- Removal of oedema and exudate
- Promotion of perfusion
- Assistance in wound contraction and closure
- Provision of a closed, moist wound-healing environment
- Assistance in preventing maceration of surrounding peri-wound area.

Special considerations

- Both gauze and foam-based Avance NPWT System dressings can be successfully used to treat DFUs
- Therapeutic delivery setting, when dealing with these types of wounds under gauze, should be set at constant negative pressure of between - 60mmHg to -80mmHg or as directed by the clinician
- Under foam, a setting of between -80mmHg to -120mmHg should be set, or as directed by the clinician
- If bone is present in the wound (or can be detected on probing the wound bed), the clinician should eliminate the possibility of osteomyelitis prior to application of the Avance NPWT System to the wound. Debridement of infected bone may be required
- NPWT can be applied if osteomyelitis is being treated with antibiotics
- If healthy bone is present within the wound, this should be covered with a wound contact layer (e.g. Mepitel®/Mepitel One with Safetac®) prior to application of the Avance NPWT System gauze or foam dressing
- Due to the shape of the foot, care is needed to ensure the dressing (foam or gauze) does not come into contact with intact skin at the edge of the wound. The provision of a film or hydrocolloid barrier around the wound may help prevent accidental damage
- The poor sensory function (neuropathy) of many individuals with diabetes may mask the signs of pressure (such as discomfort). It is important to ensure that the placement of the drain, ViewPad and drainage tubing does not cause pressure to the wound or surrounding skin. Bridging techniques can be employed to divert drainage to areas of low risk
- Dressing changes should be undertaken approximately every 48–72 hours, but not less than three times weekly for non-infected wounds, but may need to be undertaken more frequently if infected.

Precautions and warnings

- When placing the film on the wound, it should never be wrapped around the limb or digit as this may lead to a tourniquet effect. If the patient experiences any tingling or numbness during NPWT, this should be investigated. NPWT should be discontinued until the issue is resolved
- Patients with DFUs often have to wear an offloading device. Positioning of the tubing needs to be carefully planned. Each device will be different and a bridging technique might be the optimal technique to ensure that the surrounding intact skin is not compromised.

SPECIAL CIRCUMSTANCES

CARE SETTINGS TRANSITIONS

If the patient is to be moved from one care environment to another, it is the responsibility of the clinician and healthcare providers to ensure that adequate provision is made for the continuation of therapy.

USE WITH HYPERBARIC OXYGEN CHAMBER

Hyperbaric oxygen (HBO) therapy can be used in combination with NPWT; however, there are some precautions that must be observed for the safety of the patient and the treating staff.

The Avance NPWT System must not be taken into the HBO chamber as it can be a fire hazard in this oxygen-rich environment. Disconnect the patient from the pump; do not apply a clamp to the drain tubing. Instead, loosely cover the free end with an appropriate sterile dressing. Always check with the clinician for his/her preference for allowing the Avance NPWT System to be disconnected, with the dressing left in place during HBO therapy.

After HBO therapy has been completed, the dressing may be reconnected and therapy with the Avance NPWT System recommenced. It is advisable to use an alcohol wipe or replace the tubing before reconnecting the Avance NPWT System.

If the length of treatment in the HBO chamber is greater than 2 hours, consider removing the NPWT dressing prior to treatment and using an alternative dressing for this period.

USE WITH IMAGING EQUIPMENT

Some components of the Avance NPWT System dressing may be visible on some radiological images.

X-ray

In the event that a patient being treated with the Avance NPWT System requires X-ray examination, consider the following actions:

- The Avance Pump can be taken into the X-ray room and its position adjusted by the technician so that it is out of the way and there is easy access to the patient and to the X-ray machine

-
- Always check with the radiologist or technician if the dressing needs to be removed prior to examination.

Computerised Tomography (CT)

In the event that a patient being treated with the Avance NPWT System should need an examination by CT scan, consider the following actions

- The Avance Pump can be taken into the scan room and its position adjusted by the technician so that it is out of the way and there is easy access to the patient and to the scanner
- Always check with the radiologist or technician if the dressing needs to be removed prior to examination.

Magnetic Resonance Imaging (MRI)/Tomography

In the event that a patient being treated with the Avance NPWT System should need an examination by MRI, the following procedure *must* be observed for the safety of the patient and the treating staff:

- The Avance Pump must not be taken into the MRI room as it can be a hazard in this environment
- Always check with the radiologist or technician if the dressing needs to be removed prior to examination
- Ensure the pump is reattached and reactivated following the procedure, providing that the time without NPWT does not exceed two hours. In this instance, it is advisable to change the dressing before reapplying NPWT.

ALLERGIC REACTION

All components and packaging of the Avance NPWT System are latex-free. The development of irritation or erythema could indicate infection or sensitivity to the dressing components. If observed, report to the clinician immediately.

CLINICAL TROUBLESHOOTING

The Avance NPWT System is easy to operate and clinically effective. Patients can sometimes present with unique clinical challenges, especially when it comes to wound care. The following guidance is designed to assist clinicians in obtaining the optimum results for their patients.

Clinical presentation	Importance	Cause/Action
Ineffective dressing seal	High	It is very important to try and maintain a seal. Once negative pressure is applied, the foam or gauze dressing will have a wrinkled ‘raisin-like’ appearance and be firm to the touch. When the pump is turned on, the pre-set pressure is shown on the pump unit display. The pump will appear to make a noise for a few seconds as it builds up towards this pressure. If the pump continuously makes a noise for more than 45 seconds, it may be likely that the system has an air leak. If the dressing does not collapse, the system may not be closed. Inspect the dressing site and use additional adhesive film to maintain a seal. An air leakage indicator is shown on the pump display. When clear, it indicates that the system is airtight; when half-full, it indicates that there is a leak somewhere in the system but the pressure is still being maintained; when full and flashing, it indicates that there is a major air leak in the system, at which point the alarm will sound and the pressure is no longer being maintained. The instructions on the display must then be followed. It may be necessary to remove the film and consider using a soft silicone sealant (e.g.Mepiseal® with Safetac®) to achieve and maintain a seal. This product should only be applied to the intact dry peri-wound skin.

Clinical presentation	Importance	Cause/Action
Ineffective dressing seal	High	If the dressing appears to be secure but the problem persists, check: • Drainage connector is firmly attached and not kinked • Canister is not damaged (replace if necessary) • Canister seal is intact and in place (replace if necessary) For further assistance, contact your Mölnlycke Health Care representative.
Pain during therapy	Moderate/High	Analgesia may be required for some patients. If this does not help, then consider lowering pressures in 10mmHg increments until the issue resolves. If there is sudden onset of pain immediately following dressing change: check that the negative pressure is set correctly; check that the flat drain is correctly positioned and is not resting directly on the wound bed; and ensure that dressings have been applied correctly. If necessary, correct and restart therapy. If the discomfort is at the peri-wound area, check that the foam or gauze dressing is not in direct contact with intact skin. If there is a gradual increase in pain/discomfort in a wound which has previously been pain-free, check for signs of infection.

Clinical presentation	Importance	Cause/Action
Peri-wound excoriation	Moderate	Peri-wound excoriation can occur if the dressing (gauze or foam) comes into contact with intact skin at the wound margin. Remove the dressing and ensure correct dressing application. Peri-wound excoriation can also occur if wound exudate builds up within the dressing. If the patient has intermittent therapy applied and the time period for 'off' is a few minutes, consider changing the regime to a shorter 'off' time period; or consider that this therapy may not be suitable for the patient due to high levels of exudate. Address all urinary and faecal incontinence issues as per local policy if the wound is in close proximity to these areas. Check that the Avance NPWT System is working, check for signs of a poor seal ('whistling' sound, audible/visual alarm, dressing has not collapsed into the wound), make sure the tubing is not kinked or blocked. If exudate levels are high, consider increasing the negative pressure setting by -10mmHg increments as tolerated. Remember to reduce the level of negative pressure to the recommended therapeutic setting when appropriate.
Odour/smell	Moderate	Some odour may be noted at dressing change and this is normal. A significant increase in odour may be an early indication of infection. Faecal odour may indicate the presence of infection with faecal flora or the presence of bowel fistulas (abdominal wounds only). Investigate and take appropriate action.

Clinical presentation	Importance	Cause/Action
Bleeding (light)	Moderate	Some light bleeding may be seen on dressing change, especially if the previous dressing was adhered to the wound bed. If pale pink exudate is observed in the canister, monitor the levels of exudate. Consider using a wound contact layer (e.g. Mepitel®/Mepitel One with Safetac®) under the foam/gauze dressing.
Bleeding (heavy)	High	If large amounts of blood (dark red or bright red) are seen in the tubing or canister, stop Avance NPWT immediately and urgently report to the clinician. Closely monitor patients if they are receiving anticoagulation therapy.
Peri-wound bruising	Low	Minor bruising will occur if dressing material (foam or gauze) or tubing is allowed to come into direct contact with the intact skin around the wound. Remove the dressing. Inspect and document the affected area. Ensure correct placement of the foam/gauze into the wound. If the skin is broken, consider applying a dressing, such as Mepilex® Lite with Safetac®, over the damaged area prior to reapplication of the Avance NPWT System. Monitor and document peri-wound progress.
Peri-wound blistering	Moderate	Blistering may occur to the peri-wound skin if: • The film is applied too tightly • The film is pulled off without stretching it laterally • The patient has friable skin Ensure the dressing is applied and removed as instructed. Protect delicate skin with a liquid film barrier product prior to film application. Consider the use of Avance Film with Safetac to minimise the risk of blistering.

Clinical presentation	Importance	Cause/Action
Exudate volume (increase)	Moderate	In some individuals, there may be some increase in wound exudate following the initiation of the Avance® NPWT System. Monitor the amount, consistency and colour of exudate. If there is a marked increase in wound exudate production (without signs of infection e.g. pyrexia, increased pain, erythema/cellulitis), continue therapy but inform the patient's clinician. Record amount in canister to accurately assess fluid loss.
Exudate volume (decrease)	Low	It is normal for exudate levels to drop following initiation of NPWT. This is not necessarily an indication to discontinue therapy.
Exudate consistency	Moderate/High	Some changes in wound exudate consistency will normally occur following initiation of the Avance NPWT System. However, if the exudate becomes heavily blood- stained, thick and/or cloudy, changes colour, or appears to contain small bowel effluent/bile (in abdominal wounds only), stop therapy and inform the patient's clinician immediately.
Adherent gauze/foam	Moderate	Saturate adherent dressing before trying to remove it. The ingrowth of granulation tissue and/or capillaries into dressing material (gauze or foam) can occur if granulation is rapidly occurring. Granulation rates can vary. Each wound and each patient will dictate the frequency of dressing changes, along with the clinician's experience and recommended manufacturer's guidelines. Consider more frequent dressings changes for this type of patient and possible use of a wound contact layer (e.g. Mepitel/Mepitel One with Safetac) between the wound and the dressing.

Clinical presentation	Importance	Cause/Action
Infection	High	The Avance NPWT System may be of benefit in managing wounds with a high bacterial burden as it can draw bacteria-laden exudate away from the wound. Clinicians must use caution when treating infected wounds with NPWT and should consider the use of appropriate systemic antimicrobial therapy. The frequency of dressing changes may need to be increased if infection is present
Wound deterioration	High	Some changes to the wound appearance may occur during the use of the Avance NPWT System. If the wound is deemed to have deteriorated, the clinician should ensure that: • Therapy has been delivered correctly (dressing technique, pressure settings, constant/intermittent therapy) • Wound contact layer has been used (if appropriate) • Wound has been adequately debrided • Bacterial burden has been managed • Wound infection has been treated (if appropriate) If the cause of the deterioration cannot be identified, the patient's clinician should consider discontinuation of Avance NPWT and initiation of alternative wound management strategies.
Distal circulation	High	When using the Avance NPWT System to treat wounds on a limb, regularly check the circulation in the distal limb – particularly in individuals with vascular disease or circumferential wounds. Check that the film has not been circumferentially applied to any limb. This may cause a tourniquet effect. If circulation is compromised, stop NPWT immediately, remove the dressing and report to the patient's clinician.

IMPORTANT POINTS

- Check dressing periodically for leaks (listen for a whistling sound, which is indicative of a poor seal and observe air leak indicator)
- Check that the dressing has collapsed into the wound
- When using the Avance NPWT System on a limb, check the circulation to the distal portion of the limb regularly
- Check the patient regularly and assess/monitor the patient's pain status
- When using the Avance NPWT System, ensure that the wound cavity is sufficiently filled with foam or gauze, without overpacking. When negative pressure is applied, there should be no visible area without wound dressing material in the wound cavity. If there is, make a small incision in the film and fill with additional wound dressing material. Cover the incision with additional film to secure an adequate seal
- Change the Avance Canister and Avance Tubing at the same time on the basis of a visual check, according to the instructions in the Avance Pump display / alarm signal, or every three to five days but minimum once a week
- Assess the wound for signs of infection; if present, report to the patient's clinician

WARNINGS AND ALARMS

The Avance NPWT System is fitted with a sensitive warning and alarm system to ensure a safe and effective operation of the system. These alarms will alert you to the fact that something has changed, either with the wound or the pump.

If the Avance NPWT System Pump detects any faults, an audible warning signal sounds and a description of the problem appears on the display. Hints on troubleshooting appear on the unit display. Warnings shown on the pump display are illustrated in Appendix 2. Some alarms will sound and the negative pressure will be maintained – where possible. Other alarms will cause the pump to stop negative pressure until corrective action has been taken. Please examine all alarms in this event.

APPENDICES

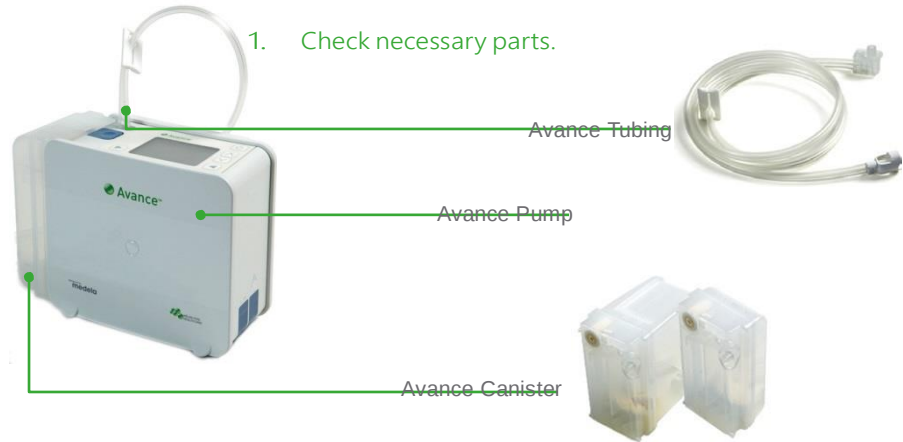
APPENDIX 1 – SAFETY INSTRUCTIONS

- The patient should be regularly monitored according to facility or institution guidelines
- The Avance Pump must remain in an upright position during use
- The Avance Pump is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the attached Electro Magnetic Compatibility (EMC) information. Portable and mobile RF (Radio Frequency) communication devices (mobile telephones) can affect the Avance Pump
- The Avance Pump must not be used:
 - If the power cord or plug are damaged
 - If the device is not functioning properly
 - If the device is damaged
 - If the device has apparent safety defects
- Keep the Avance Pump and associated products away from hot surfaces
- Separation from the power supply occurs by unplugging the charger or when the pump is removed from the docking station
- The Avance Pump must not be used for suctioning explosive, easily flammable or corrosive liquids
- The tubing supplied with the device must not come into direct contact with the wound area
- Do not disconnect the pump power supply by pulling on the mains connecting cable
- Do not place the Avance Pump, charger or docking station in water or other liquids and keep the charger connector away from moisture or immersion in water
- Do not dry the Avance Pump with microwaves.

APPENDIX 2 - SET-UP

Preparation for Use

Use only after instruction by trained personnel. Wear gloves for all operations.

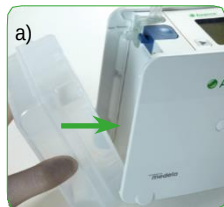
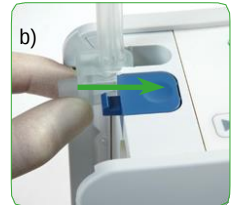


2. Connect Avance Tubing.

a) Open external packaging.

Keep the inner packaging, as it is used for the functional check.

b) Insert the tubing base into the pump as shown (straight push).

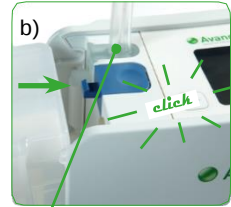


3. Click in Avance Canister.

Open external packaging.

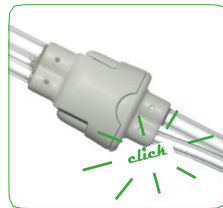
a) Slip the bottom of the canister into the pump.

b) "Click" into place.



Canister secures tubing

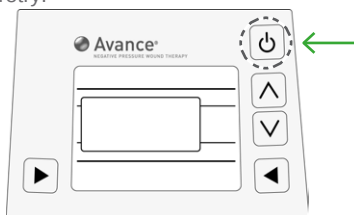
4. Connect the ViewPad tubing or the drain adaptor to the canister tubing.



5. Switch Avance Pump ON by pressing [].

The pump will do self-test and start running immediately. You should hear the motor running for a short time until the pressure is built up. If the motor keeps running for more than 30 sec.

– check system and
retry.



If the self-test is not successful, follow instructions shown on the display or see the Alarms chapter.

Administrative Mode

The default settings of the Avance Pump are -60 mmHg and constant mode.

The pressure level should always be set according to clinician's instruction.

For guidance the recommended pressure levels are:

- Foam dressing -120 mmHg
- Gauze dressing -80 mmHg.

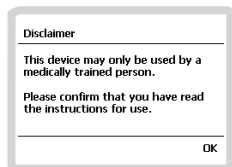
The set pressure is measured and controlled at the end of the conocal connector on the canister tube.



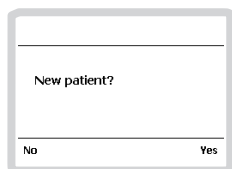
1. Switch Avance Pump ON in Administrative mode, press and hold [▶], press [⏻].

Self-test starts

If the self-test is not successful, follow instructions shown on the display or see the Alarm chapter.



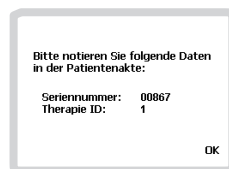
2. Acknowledge disclaimer. Press [OK] [◀] to confirm.



New patient? Yes/No

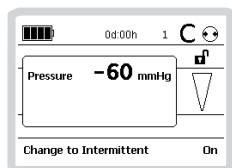
[Yes] means that Avance Pump will issue a new therapy ID number (= new patient).

This number can be noted in the patient's file.



The therapy ID number is displayed in the information field.

[No] means that the therapy ID number and settings remains unchanged (= same patient).



3. If yes

Press [Yes] [▶] to confirm.



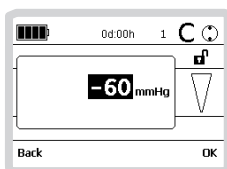
Press $\frac{\circ}{\circ}$ OK $\frac{\circ}{\circ}$ [] to enter the main display.

4. If no

Press $\frac{\circ}{\circ}$ No $\frac{\circ}{\circ}$ ] to confirm and enter the main display.

Set the pressure level and therapy mode according to clinicians instruction.

To change the pressure level



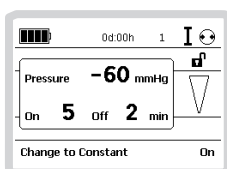
5. Press the Selection buttons [] or [] to set pressure level.
6. Press “OK” [] to confirm and enter the main display.
7. To return to the main display, press [].

If the pressure level is not confirmed, the pump will switch back to the old settings and returns automatically to the main display after 5 seconds.

To change the therapy mode

Constant mode – C

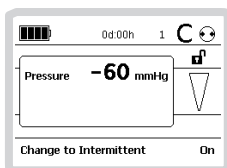
The pre-selected pressure is built up and kept constant.



8. To change from intermittent mode to constant mode, press [] “Change to Constant” and press “On” [].

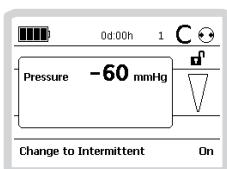
Intermittent mode – I

The pre-selected pressure is built up and the pre-selected time intervals are used.

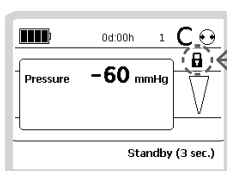


9. To change from constant mode to intermittent mode, press [] “Change to Intermittent” and press “On” [].

10. Apply the dressing, see Wound Dressing Guidelines chapter. Connect the canister tubing to the dressing.



11. Press “On” [] to start the pump.



1 minute after the last button has been pressed, the Avance Pump switches into patient mode automatically and the display is locked.

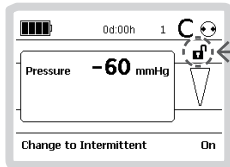
1 minute after the last button has been pressed,

the backlight turns off. In case of pressing any button or alarm goes off the backlight will turn on.

The settings can only be changed when the pump is in the administrative mode.

The settings possible to change are the Pressure, Unit pressure, On time, Off time, Language and Time zone. Pump number, Pump run-time and Version can only be viewed and not changed.

Change settings



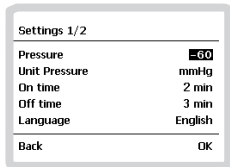
1. To enter the administrative mode, unlock the display by press and hold [▶], press [⏻].

2. Press the “soft” buttons [▶] + [◀] at the same time.
[▶] [◀]

3. To change setting, choose with the “Selection buttons” [⬆] or [⬇].

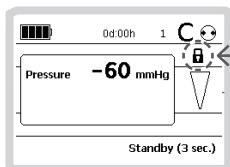
Selection	
	-60 to -200 mmHg (-8 to -27 kPa)
	kPa /
	mmHg 1
	- 8 min.
	1 – 8
	min Languages according

Selection	
	+0 – 12 hours
	GMT
	as
	displayed
	as
	displayed



4. Press “OK” [▶] to select.
5. To change value, choose with the “Selection buttons” [⬆] or [⬇].
6. Press “OK” [▶] to confirm.

If the changed setting is not confirmed, the pump will switch back to the old settings.



7. Press “Back” [▶] to exit settings.
- 1 minute after the last button has been pressed, the Avance Pump switches into patient mode

automatically and the display is locked.

Warnings and alarms

Avance Pump distinguishes between faults/warnings and alarms.

If Avance Pump detects any of these situations, an acoustic warning signal sounds and a description of the problem appears on the display. Press **[Mute]** **[]** to mute and acknowledge the alarm. The acoustic alarm is suppressed for 1 minute if the problem is not solved.



Turn ON

Switch Avance Pump ON by pressing **[Power]** **[]**

Self-test starts

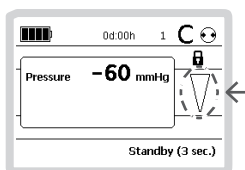
If the self-test is not successful, follow instructions shown on the display or see the Alarms chapter.

When the pump is turned on in this mode, last settings (therapy mode and pressure level) are used by default.

Check pressure

The set pressure will be shown on the display. The motor will run for a few seconds to build up the pressure. If it runs continuously for more than 30 seconds, check system for leaks and try again.

The set pressure is measured and controlled at the end of the conical connector on the canister tube.



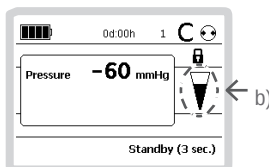
Air leakage indicator

An air leakage indicator is shown on the display to visualise if there

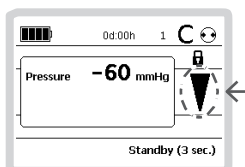
a) is an air leakage in the system.
a) When the indicator is "empty", the system is air tight.

b) When the indicator is "half full" there is an air leak in the system, but the pressure and therapy is maintained in accordance with the set pressure.

c) When the indicator is "full" and flashes, there is a big air leak in the system. The air leakage alarm will go off within 2 minutes if the set pressure is not maintained. Follow the instructions shown on the display, or see Alarms chapter.



b)



c)

Standby

Change the Avance Pump into the standby mode.

Press the "Standby" button **[Standby]** **[]** > 3 sec.] and the pressure will be turned OFF.

If the pump is in Standby mode for more than 5 minutes, an alarm will go off, follow instructions shown on the display or see the Alarms chapter.

Turn OFF

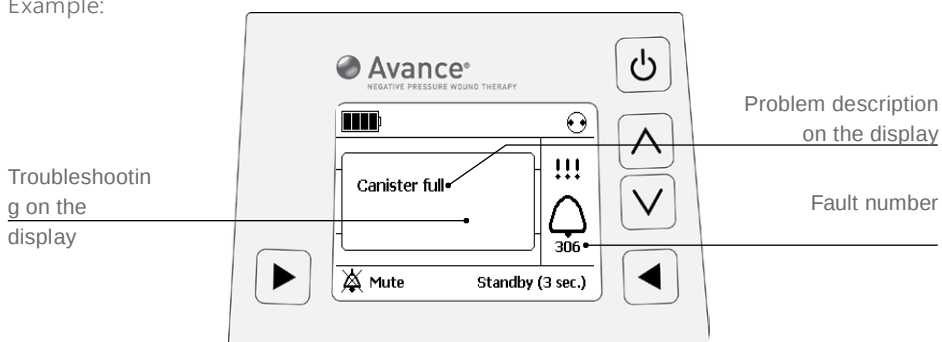
Press [ > 3 sec.] and the pump will be turned OFF.

Alarms

The Avance Pump has alarm functions for patient safety. If the pump detects any situations where the therapy can not be maintained, an acoustic alarm sounds, a fault number and a description of the problem appears on the display. For explanation of the fault number, see the Alarm Table in this chapter.

The pump distinguishes between “Warning”, “Alarm” and “Internal fault”.

Example:



If the pump is turned off and therapy discontinued for more than 2 hours, dressing should be replaced, wound irrigated and therapy restarted according to clinician's instructions.

“Warning”

- Pump operation continues, an acoustic alarm sounds and the fault number is shown on the display.

**“Alarm”**

- Pump operation halts, an acoustic alarm sounds and the fault number is shown on the display.



When the Warnings / Alarms goes off an acoustic alarm sounds.

A description of the “Warning” or “Alarm” will be shown on the display.

1. Press to mute and acknowledge the alarm.
The acoustic alarm is suppressed for 1 minute if the problem is not solved.
2. Follow the instruction shown on the display and see Alarm Table.
3. If the problem can not be solved, turn OFF > 3 sec.]
Avance® Pump and consult your contact person for further instructions.

“Internal fault”

- Pump operation stops and an acoustic alarm sounds, “Internal fault” is shown on the display.

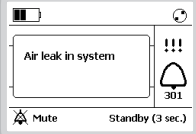
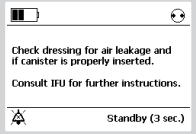
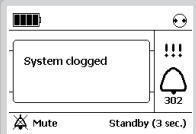
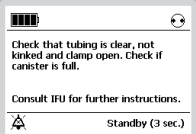
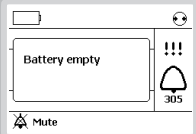
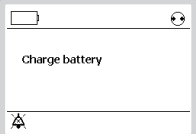
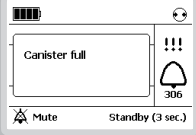
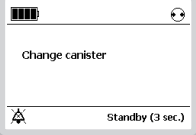


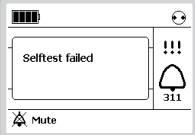
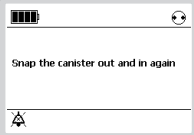
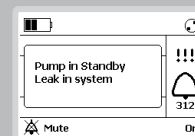
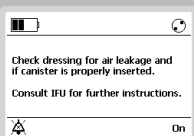
When the Internal fault alarm goes off an acoustic alarm sounds.

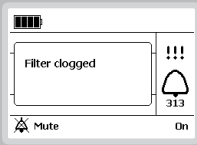
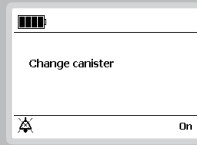
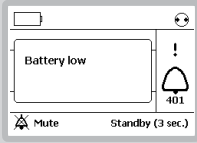
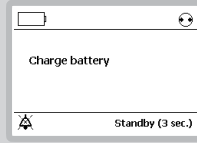
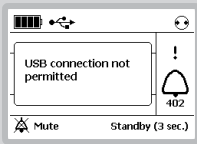
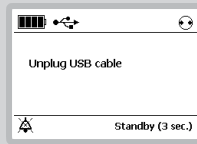
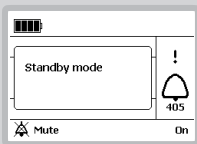
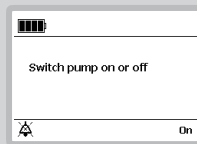
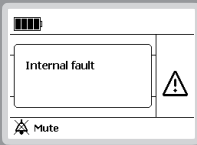
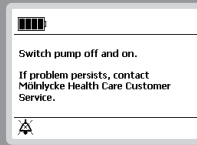
“Internal fault” will be shown on the display.

1. Press > 3 sec.] and the pump will be turned OFF.
2. Restart the pump by pressing and the pump will be turned ON.
3. If the Internal fault alarm remains, turn OFF > 3 sec.]
Avance Pump and contact Mölnlycke Health Care Customer Service.

Alarm Table

Fault number	Problem description on the display	Troubleshooting on the display	Remarks/potential cause of fault	Pressure
301 Alarm			Dressing: - Check dressing for air leakage. Press firmly around the edges of the dressing, around the drain tube or on the ViewPad. - Apply some additional film dressing to seal the leaking area. Connectors: - Ensure that the tube connected to the dressing is properly connected to the Canister tube. - Ensure that the canister tube is inserted straight into the pump. Canister: - Ensure that the canister is properly inserted, release the canister and reposition. - Ensure that the O-ring/gasket, placed beside the canister tubing on the pump is not missing. Additional O-ring is available via Mölnlycke Health Care representative.	✓
302 Alarm			Tubing: - Ensure that the tubing is not twisted, kinked or clamped. - If the canister tube is clogged, change the tube. Canister: - If canister is full or filter clogged, replace canister.	✓
305 Alarm			- If canister is full or filter clogged, replace canister. Recharge the battery either by placing the Avance Pump in the Docking Station or plug in the charger to the electrical outlet port on the pump.	✗
306 Alarm			Remaining time of battery is approximately 15 minutes. Change the canister, see chapter "Change Avance Canister and Avance Tubing".	✓

- E n s u r e			that the tubing is not twisted, kinked or clamped.	
t	 Selftest failed !!! 311 Mute	 Snap the canister out and in again !!!		
312	 Pump in Standby Leak in system !!! 312 Mute On	 Check dressing for air leakage and if canister is properly inserted. Consult IFU for further instructions. !!! On	Dressing: - Check dressing for air leakage. Press firmly around the edges of the dressing, around the drain tube or on the ViewPad. - Apply some additional film dressing to seal the leaking area. Connectors: - Ensure that the tube connected to the dressing is properly connected to the Canister tube. - Ensure that the canister tube is inserted straight into the pump. Canister: - Ensure that the canister is properly inserted, release the canister and reposition. - Ensure that the O-ring/gasket, placed beside the canister tubing on the pump is not missing. Additional O-ring is available via Mölnlycke Health Care representative.	

the display					
313	Alarm			Change canister, see chapter "Change Avance Canister and Avance Tubing"	✗
401	Warning			Recharge the battery either by placing the Avance® Pump in the Docking Station or plug in the charger to the electrical outlet port on the pump. Remaining time of battery is approximately 30 minutes.	✓
402	Warning			Unplug USB cable	✓
405	Warning			If the pump is in Standby mode for more than 5 minutes, an alarm will go off. To continue therapy press "On" [On] or switch OFF the pump by pressing [Off] > 3 sec.].	✗
	Internal fault			Restart the pump. If internal fault remains, turn OFF by pressing [Off] > 3 sec.] and contact Mölnlycke Health Care Customer Service.	✗

If fault repeats, note the fault number, switch off the pump and contact Mölnlycke Health Care Customer Service.

If the pump is turned off and therapy discontinued for more than 2 hours, the dressing should be replaced, wound irrigated and therapy restarted according to clinician's instruction

