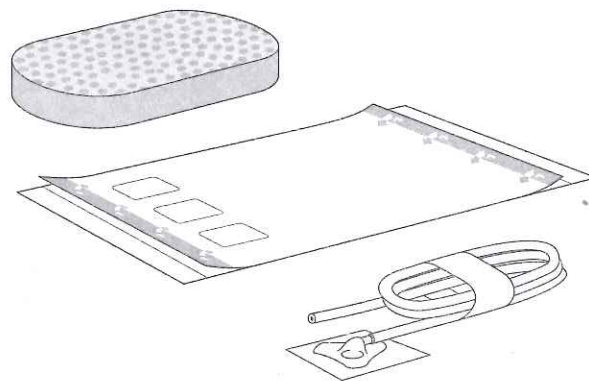




Avance®

NEGATIVE PRESSURE WOUND THERAPY

Avance® Foam Dressing Kit incl. Transparent film, Transfer Pad
Wound foam, transfer pad and transparent film



STERILE EO

Single use
Usage unique



Patent pending

CE 0086



MÖLNLYCKE
HEALTH CARE

Manufacturer

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Avance® Foam Dressing Kit incl. Transparent film, Transfer Pad

1



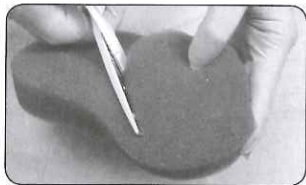
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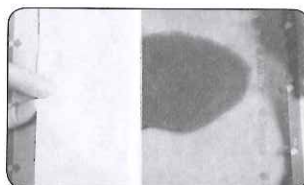
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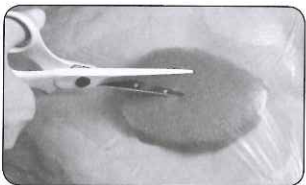
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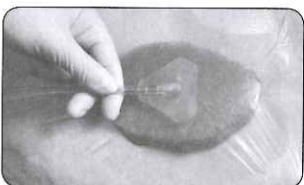
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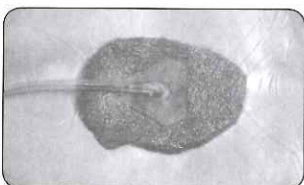
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11



12





- en** Do not use if package is damaged
- de** Bei beschädigter Verp. verwerfen
- fr** Ne pas utiliser si l'emballage est endommagé
- es** No utilizar si el envase está dañado
- nl** Niet gebr als verpakk beschadigd is
- sv** Skall inte användas om förpackningen är skadad
- it** Non utilizzare se la confezione è danneggiata
- fi** Älä käyttää jos pakkaus vaurioitunut
- pt** Não usar se embalagem danificada
- da** Brug ikke, hvis pakken er beskadiget
- no** Må ikke brukes hvis forpakningen er skadet



- en** This product nor the packaging contain Natural Rubber Latex (NRL).
- de** Dieses Produkt sowie seine Verpackung ist latexfrei.
- fr** Ni ce produit, ni l'emballage ne contiennent de Latex Naturel de Caoutchouc.
- es** Este producto o su empaquetado no contienen látex de caucho natural.
- nl** Dit product en zijn verpakking bevatten geen Natuurlijk Rubber Latex (NRL).
- sv** Varken denna produkt eller förpackning innehåller naturgummilates.
- it** Né il prodotto né il confezionamento contengono lattice di gomma naturale.
- fi** Tämä tuote tai sen pakkaus eivät sisällä luonnonkumilateksia.
- pt** Este produto, tal como a sua embalagem, não contém látex de borracha natural.
- da** Hverken produktet eller emballagen indeholder naturgummilates (NGL).
- no** Hverken produktet eller pakningen inneholder naturgummilates.

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en Avance® Foam Dressing Kit incl. Transparent film, Transfer Pad Wound foam, transfer pad and transparent film

Intended use

The Avance® NPWT system, with associated products, is intended to help promote wound healing, including drainage and removal of infectious material or other fluids, by application of constant and/or intermittent negative pressure. The Avance NPWT system is intended for use with patients in healthcare facilities and home care settings by trained medical personnel adhering to the instruction for use. The Avance system is designed for use on a wide range of wounds indicated for NPWT.

The Avance NPWT system is indicated for use with the following types of wounds:

- Traumatic
- Surgical (sternal/abdominal/extremity)
- Dehisced wounds
- Chronic wounds including pressure ulcers, diabetic foot ulcers and venous leg ulcers
- Partial-thickness burns
- Flaps and grafts

Contraindications for treatment with the Avance NPWT system:

- Direct positioning of NPWT over exposed organs, large veins and arteries, anastomotic sites, tendons or nerves
- Malignant wounds
- Untreated osteomyelitis
- Non-enteric or unexplored fistulas
- Undebrided wounds with necrotic tissue and eschar present

Application instructions

To apply, use clean/aseptic or sterile techniques in accordance with local protocol. The Avance system is only to be used by qualified and trained personnel.

Unfold the first spread to reveal pictures that correspond to the following text:

1. Cleanse and debride the wound bed as instructed by the clinician.
2. Pat dry.
3. Protect bones/tendons with Mepitel® if applicable. Apply skin protector/skin sealant on periwound skin if required.
4. Cut the foam into an appropriate size corresponding to the dimensions of the wound cavity. Do not cut the foam above the wound site. Remove any fragments from foam edges to protect the wound from loose particles. Sufficiently fill the wound cavity without overpacking.
5. Cut the film to the appropriate size allowing an overlap of 3-5 cm onto surrounding skin.
6. Cover the foam with film. Do not stretch the film. If no airtight seal is obtained, use additional film for sealing, consider use of sealing accessories or remove dressing and start again.
7. Cut a hole in the film < 1 cm in diameter.
8. Remove the release film of the Transfer Pad and apply the Transfer Pad directly over the cut hole in the film. Press gently to fixate the Transfer Pad on top of the film.
9. Connect the Transfer Pad tubing to the canister tubing.
10. Attach the canister to the pump.
11. Turn on the pump.
12. Once the negative pressure is applied, the dressing will have a "raisin-like" appearance and be firm to the touch.

Frequency of change and dressing removal

Dressings (wound contact layer, wound filler, wound cover, transfer pad) should be changed every 48 to 72 hours, but no less than 3 times a week, or as instructed by the clinician. The frequency of dressing changes should be based on an evaluation of the wound condition rather than standard recommendations.

Remove the film and wound filler gently. If adherence of wound filler to wound bed is observed, consider moistening the filler material. If the patient experiences pain during dressing removal, consider the use of pain relief medication, as instructed by the clinician, when changing dressings.

Dispose of the dressing in accordance with local guidelines/regulations.

Information related to daily use

Do not expose the dressing to extensive contact with water during bathing/showering. Splashing is allowed.

If it is necessary to disconnect the pump, the time elapsed without applied negative pressure must comply with the clinician's instruction.



Warnings

Do not position Avance dressings on exposed organs, large veins and arteries, tendons, bones or nerves. To prevent puncture of blood vessels or organs, and damage to tendons, bones and nerves, sharp edges or bone fragments must be eliminated from the wound area or covered with a non-adherent wound contact layer (e.g. Mepitel).

If more than one piece of wound filler material is used, always count the pieces and document the total in the patient's notes. This is to ensure that all pieces are removed when the dressing is changed.

Do not cut the wound filler above the wound site, as fragments may fall into the wound. Make sure no fragments are left in the wound when the dressing is changed.

Always document the use of Mepitel in the patient's notes to ensure that no Mepitel is left in the wound when the dressing is changed.

If bleeding suddenly develops or an ongoing bleed increases during NPWT, immediately discontinue treatment, leave dressing in place, consult medicinal assistance and take measures to stop the bleeding.

Do not place wound filler into unexplored or blind tunnels or non-enteric fistulas.

Do not use NPWT on wounds with necrotic tissue or eschar unless adequately debrided.

Ensure contact between all pieces of wound filler material for even distribution of negative pressure.

Do not overpack wound filler into any area of the wound, as this could damage tissue, affect exudate removal, or affect delivery of negative pressure.

Do not overlap wound filler onto intact skin.

For wounds smaller than the Transfer Pad, protect periwound skin, e.g. with film and wound filler, in order to avoid imprints caused by the Transfer Pad.

If risk for imprints from the tubing or the clamp on the Transfer Pad, place e.g. a piece of Mepilex® Lite, an absorbent soft silicone dressing, between skin and tubing/clamp.

If the dressing does not have a "raisin-like" appearance when the negative pressure is applied, check that the Transfer Pad is placed directly over the cut hole in the film.

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

Precautions

In-growth of tissue into wound filler material may occur if the dressing is not changed in accordance with recommendations or as appropriate for the wound condition of the individual patient.

Superficial or retention sutures should be protected in conjunction with NPWT treatment.

Extra care should be taken when treating wounds in close proximity to organs or large veins and arteries.

Application of certain skin protection products e.g. zinc paste or skin lotions to the patient's skin prior to application of the film, can affect the ability of the film to adhere securely.

If Transfer Pad tubing is kinked, blockage may occur.

Avance Transparent Film should not be used on patients who are sensitive to acrylic adhesive.

Stretching the film during application may cause damage to the surrounding skin when negative pressure is applied.

Do not reuse. If reused performance of the product may deteriorate, cross contamination may occur.

Sterile. Do not use if inner package is damaged or opened prior to use. Do not re-sterilise.

For additional information on the Avance system, including additional safety considerations, see the Avance Negative Pressure Wound Therapy Instructions for use, for the Avance Pump.

Made in Finland

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