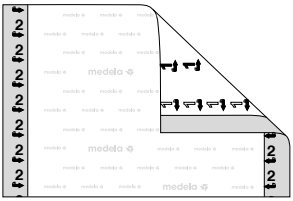
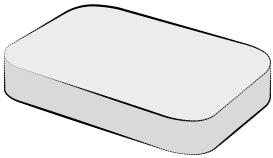
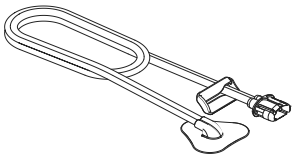
Invia® Foam Dressing Kit with FitPad

NEGATIVE PRESSURE WOUND THERAPY

- EN Instructions for use
- ES Instrucciones de uso
- PT Instruções de utilização
- FR Mode d'emploi
- DE Gebrauchsanweisung
- IT Istruzioni per l'uso







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CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

Only for use with Invia Negative Pressure Wound Therapy Systems

Device description

The Invia Foam Dressing Kit with FitPad consists of a foam pad, a suction interface (Invia FitPad) and Transparent Film (one or more pieces depending on the kit size).
The Invia Foam Dressing Kit with FitPad is available in four sizes

Description	Kit contents			
Size	Small (200.8905)	Medium (200.8906)	Large (200.8907)	X-Large (200.8908)
Foam dimensions (Length x Width x thickness)	10 cm x 8 cm x 3 cm	19 cm x 12.5 cm x 3 cm	25 cm x 15 cm x 3 cm	60 cm x 30 cm x 1.5 cm
Foam pad	1	1	1	1
Transparent Film	1	2	2	5
Suction pad (FitPad)	1	1	1	1

Invia Foam Dressing Kit with FitPad – Small

REF 087.6221 (3 pcs of 200.8905)
REF 087.6225 (15 pcs of 200.8905)

Invia Foam Dressing Kit with FitPad – Medium

REF 087.6222 (3 pcs of 200.8906)
REF 087.6226 (15 pcs of 200.8906)

Invia Foam Dressing Kit with FitPad – Large

REF 087.6223 (3 pcs of 200.8907)
REF 087.6227 (15 pcs of 200.8907)

Invia Foam Dressing Kit with FitPad – X-Large

REF 087.6224 (3 pcs of 200.8908)

Intended use and therapy safety information

The Invia Foam Dressing Kit with FitPad is intended for use in conjunction with the Invia Motion and Invia Liberty Negative Pressure Wound Therapy (NPWT) Systems. The Invia Motion and Invia Liberty NPWT Systems are intended for use in acute, extended and home care settings. Users are directed to the Invia Motion and Invia Liberty NPWT System labeling for additional safety information and instruction for use. To help ensure safe and effective use, the Invia Foam Dressing Kits with FitPad are to be used only with the approved therapy units.
The components of the Invia Foam Dressing Kit with FitPad are packaged sterile and are for single use only. Do not use if sterile package is damaged or opened prior to use.
To apply Invia Foam Dressing Kit with FitPad, use clean/aseptic or sterile techniques in accordance with local protocol.
Important: Failure to consult a physician and carefully read and follow all therapy unit and dressing instructions for use and safety information prior to each use may lead to inadequate performance of the product and/or potential for serious or fatal injury. Do not adjust therapy unit settings or use unit without directions from or supervision by the prescribing physician.

Indications for use

The Invia Foam Dressing Kit with FitPad in conjunction with the Invia Motion and Invia Liberty Negative Pressure Wound Therapy (NPWT) Systems is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as when used on open wounds it creates an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material.
When used on closed surgical incisions, the Invia Foam Dressing Kit with FitPad is also intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of Negative Pressure Wound Therapy.
The Invia Foam Dressing Kit with FitPad is appropriate for use for the following indications:

- Acute or sub-acute wounds
- Chronic wounds
- Dehisced wounds
- Pressure ulcers
- Diabetic/neuropathic ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Partial thickness burns
- Flaps and grafts
- Closed surgical incisions

Contraindications

- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Malignancy in wound (with exception of palliative care to enhance quality of life)
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site of blood vessels or bypasses
- Exposed organs

Warnings and safety instructions

WARNING
Indicates a potentially hazardous situation which,if not avoided, could result in death or serious injury.

CAUTION
Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

Safety related tip
Indicating useful information about the safe use of the device.

WARNINGS
Invia Foam Dressing Kit with FitPad is intended to be used in conjunction with the Invia Motion and Invia Liberty Negative Pressure Wound Therapy Systems. Please refer to the specific product instructions for use prior to initiating therapy.

Bleeding: With or without using therapy, certain patients are at high risk of bleeding complications. The following types of patients are at an increased risk of bleeding, which, if uncontrolled, could be potentially fatal.

- Patients who have weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to:
  - Suturing of the blood vessel (native anastomosis or grafts)/organ
  - Infection
  - Trauma
  - Radiation
- Patients without adequate wound hemostasis
- Patients who have been administered anticoagulants or platelet aggregation inhibitors
- Patients who do not have adequate tissue coverage over vascular structures

If therapy is prescribed for patients who have an increased risk of bleeding complications, they should be treated and monitored in a care setting deemed appropriate by the treating physician.

If active bleeding develops suddenly or in large amounts during therapy, or if frank (bright red) blood is seen in the tubing or in the canister, immediately stop therapy, leave dressing in place, take measures to stop the bleeding and seek immediate medical assistance. The therapy units and dressings should not be used to prevent, minimize or stop vascular bleeding.

Protect vessels and organs: All exposed or superficial vessels and organs in or around the wound must be completely covered and protected prior to the administration of therapy. Always ensure that foam dressings do not come in direct contact with vessels or organs. Use of a thick layer of natural tissue should provide the most effective protection. If a thick layer of natural tissue is not available or is not surgically possible, multiple layers of fine-meshed, non-adherent material or bioengineered tissue may be considered as an alternative, if deemed by the treating physician to provide a complete protective barrier. If using non-adherent materials, ensure that they are secured in a manner as to maintain their protective position throughout therapy. Caution should be taken when treating large wounds that may contain hidden vessels, which may not be readily apparent. The patient should be closely monitored for bleeding in a care setting deemed appropriate by the treating physician.

Infected blood vessels: Infection may erode blood vessels and weaken the vascular wall which may increase susceptibility to vessel damage through abrasion or manipulation. **Infected blood vessels are at risk of complications, including bleeding, which, if uncontrolled, could be potentially fatal. Extreme caution should be used when therapy is applied in close proximity to infected or potentially infected blood vessels.** (Refer to protect vessels and organs section above.)

Hemostasis, anticoagulants and platelet aggregation inhibitors: Patients without adequate wound hemostasis have an increased risk of bleeding, which, if uncontrolled, could be potentially fatal. These patients should be treated and monitored in a care setting deemed appropriate by the treating physician.
Caution should be used in treating patients on doses of anticoagulants or platelet aggregation inhibitors thought to increase their risk for bleeding (relative to the type and complexity of the wound). Consideration should be given to the negative pressure setting and therapy mode used when initiating therapy.

Hemostatic agents applied at the wound site: Non-sutured hemostatic agents (for example, bone wax, absorbable gelatin sponge, or spray wound sealant) may, if disrupted, increase the risk of bleeding, which, if uncontrolled, could be potentially fatal. Protect against dislodging such agents. Consideration should be given to the negative pressure setting and therapy mode used when initiating therapy.

Sharp edges: Bone fragments or sharp edges could puncture protective barriers, vessels, or organs causing injury. Any injury could cause bleeding, which, if uncontrolled, could be potentially fatal. Beware of possible shifting in the relative position of tissues, vessels or organs within the wound that might increase the possibility of contact with sharp edges. Sharp edges or bone fragments must be eliminated from the wound area or covered to prevent them from puncturing blood vessels or organs before the application of therapy. Where possible, completely smooth and cover any residual edges to decrease the risk of serious or fatal injury, should shifting of structures occurs. Use caution when removing dressing components from the wound so that wound tissue is not damaged by unprotected sharp edges.

Infected wounds: Infected wounds should be monitored closely and may require more frequent dressing changes than non-infected wounds, dependent upon factors such as wound conditions and treatment goals. Refer to dressing application instructions for details regarding dressing change frequency. As with any wound treatment, clinicians and patients/caregivers should frequently monitor the patient's wound, periwound tissue and exudate for signs of infection, worsening infection, or other complications. Some signs of infection are fever, tenderness, redness, swelling, itching, rash, increased warmth at the wound or periwound area, purulent discharge, or strong odor. Infection can be serious, and can lead to complications such as pain, discomfort, fever, gangrene, toxic shock, septic shock and/or fatal injury. Some signs or complications of systemic infection are nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucus membranes, disorientation, high fever, refractory and/or orthostatic hypotension, or erythroderma (a sunburn-like rash).
If there are any signs of the onset of systemic infection or advancing infection at the wound site, contact a physician immediately to determine if therapy should be discontinued.

Osteomyelitis: The therapy system should NOT be initiated on a wound with untreated osteomyelitis. Consideration should be given to thorough debridement of all necrotic, nonviable tissue, including infected bone (if necessary), and appropriate antibiotic therapy.

Protect tendons, ligaments and nerves: Tendons, ligaments and nerves should be protected to avoid direct contact with foam dressings. These structures may be covered with natural tissue, meshed non-adherent material, or bioengineered tissue to help minimize risk of desiccation or injury.

Foam placement: Always use dressings from sterile packages that have not been opened or damaged. Do not place any foam dressing pieces into blind/unexplored tunnels. Do not force foam dressings into any area of the wound, as this may damage tissue, alter the delivery of negative pressure, or hinder exudate and foam removal. Always count the total number of pieces of foam used in the wound and document that number on the Transparent Film and in the patient's chart. Also document the dressing change date on the Transparent Film.

Foam removal: Foam dressings are not bioabsorbable. **Always count the total number of pieces of foam removed from the wound and ensure the same number of foam pieces was removed as placed.** Foam left in the wound for greater than the recommended time period may foster ingrowth of tissue into the foam, create difficulty in removing foam from the wound, or lead to infection or other adverse events. Regardless of treatment modality, disruption of new granulation tissue during any dressing change may result in bleeding at the wound site. Minor bleeding may be observed and considered expected. However, patients with increased risk of bleeding, as described in the Warnings section under Bleeding, have a potential for more serious bleeding from the wound site.
If significant bleeding develops, immediately discontinue the use of the therapy system, take measures to stop the bleeding and do not remove the foam dressing until the treating physician or surgeon is consulted. Do not resume the use of the therapy system until adequate hemostasis has been achieved and the patient is not at risk of continued bleeding.

Acrylic adhesive: The Invia Transparent Film has an acrylic adhesive coating, which may present a risk of an adverse reaction in patients who are allergic or hypersensitive to acrylic adhesives. If a patient has a known allergy or hypersensitivity to such adhesives, do not use the therapy system. If any signs of allergic reaction or hypersensitivity develop, such as redness, swelling, rash, urticaria, or significant pruritus, discontinue use and consult a physician immediately. If bronchospasm or more serious signs of allergic reaction appear, seek immediate medical assistance.

Defibrillation: Remove the dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit transmission of electrical energy and/or patient resuscitation.

Magnetic Resonance Imaging (MRI):

- Therapy Unit: Invia NPWT Systems are not for use in the Magnetic Resonance (MR) Environment, so do not take an Invia NPWT device into this environment.
- Dressings: After disconnecting from the Invia NPWT System, dressings can typically remain on the patient with no risk in a MR environment (all components are electrically nonconductive and nonmagnetic items).

Hyperbaric Oxygen Therapy (HBOT):

- Therapy Unit: Do not bring Invia NPWT Systems into HBOT Chamber
- Dressings: After disconnecting the Invia NPWT System from the dressing, either (i) replace the Invia Foam Dressing with another HBOT compatible material during the hyperbaric treatment or (ii) cover the unclamped end of the tubing with moist cotton gauze and completely cover the Invia Foam Dressing (including tubing) with a moist towel throughout the treatment in the chamber. For Hyperbaric Oxygen Therapy, the tubing must not be clamped.

Course of therapy: Invia Negative Pressure Wound Therapy Instructions advise 24 hours therapy without interruption. If therapy is discontinued for more than 2 hours, the dressing should be replaced and therapy restarted by a healthcare professional. If the therapy needs to be interrupted, the tubing should be clamped and the ends of the tubing protected.

CAUTIONS

The following statements describe conditions that may require special care for the safe and effective use of the Invia Foam Dressing Kit with FitPad.

- Patients receiving anticoagulant therapy or platelet aggregation inhibitors, actively bleeding or have weakened blood vessels or organs.
- Patients suffering from difficult wound hemostasis.
- Patients untreated for malnutrition.
- Noncompliant or combative patients.
- Patients suffering from wounds in close proximity to blood vessels or delicate fascia.
- Patients with infected wound or osteomyelitis.
- Patients with Spinal Cord Injury (sympathetic nervous system stimulation): in the event a patient experiences autonomic dysreflexia (sudden changes in blood pressure or heart rate in response to stimulation in response to stimulation of the sympathetic nervous system), discontinue Invia NPWT therapy to help minimize sensory stimulation and seek immediate medical assistance.
- Wounds that involve an enteric fistula.
- Use near vagus nerve (bradycardia).
- Circumferential dressing application.
- The device has not been studied on pediatric patients.
- Patient size and weight should be considered when prescribing this device.
- The use of negative pressure presents a risk of tissue ingrowth into the foam. Tissue ingrowth may be reduced by reducing therapy pressure, using a wound contact layer or by increasing the frequency of dressing changes.
- As a condition of use, this device should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which Invia Foam Dressing Kit with FitPad is being used.
- Ensure that tubing is installed completely and without any kinks to avoid leaks or blockages in the suction circuit.
- Underlying structures, such as tendons, ligaments and nerves should be covered with natural tissue or a non-adherent dressing layer prior to applying the foam dressing.
- Maintain regular monitoring of the wound site during therapy to ensure therapeutic treatment and patient comfort.
- Upon dressing changes, ensure that all pieces of foam are removed from the wound.
- As with all adhesive products apply and remove the dressing carefully from sensitive or fragile skin to avoid skin tripping, especially after frequent dressing changes.
- Do not use if packaging is breached or damaged.
- For maximum benefit on closed surgical incision, the Invia negative pressure therapy should be applied immediately post-surgery to clean surgically closed wounds. It is to be continuously applied for a minimum of two days up to a maximum of seven days, with regular dressing changes everty 48 to 72 hours. All dressing changes should be applied under direct medical supervision. The Invia therapy system will not be effective in addressing complications associated with the following:

- Ischemia to the incision or the incision area
- Untreated or inadequately treated infection
- Inadequate hemostasis of the incision
- Cellulitis of the incision area

Dressing application for wound management

Wound preparation

Remove and discard previous dressing per local protocol. Please refer to Dressing Removal section for more details..

WARNING

Inspect the wound thoroughly to ensure that all pieces of dressing components have been removed.

- **Thoroughly clean and debride the wound as instructed by a physician.**
- **Protect the periwound skin from exposure to moisture and adhesive.**

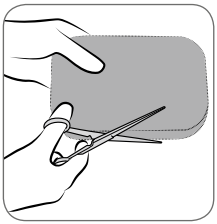
Dressing application

To be performed by healthcare professional only.

Do not use if sterile package is damaged or opened prior to use.

When applying Invia Foam Dressing Kit with FitPad, use clean/aseptic or sterile techniques per local protocol.

Step 1 – Apply the foam



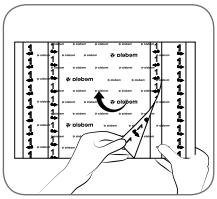
Assess and document wound dimension.

- Cut the foam to fit the size and shape of the wound.
- Place the foam into the wound cavity. Foam should fill the wound cavity without overlapping onto intact skin.
- If required, a non-adherent layer may be applied to the wound prior to placing the foam into the wound bed.

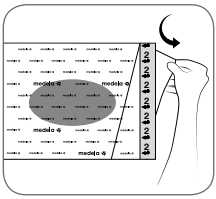
WARNINGS

- Foam should be cut to fit loosely into the wound bed. Do not tightly pack or force foam into any areas of the wound.
- Do not cut the foam directly over the wound bed to avoid foam fragments from falling into the wound. Rub the edges of the foam to remove any loose fragments after cutting.
- If multiple pieces of foam are needed to cover the wound bed, count and record how many foam pieces have been used.
- If a tunnel exists, cut the foam longer than the tunnel to ensure that contact is made with the foam in the primary wound bed/cavity. If using foam in a tunnel ensure it is wrapped in a non-adherent layer to prevent any breakage at removal.
- Do not place foam into blind or unexplored tunnels.

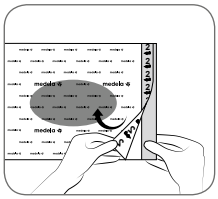
Step 2 – Apply Transparent Film



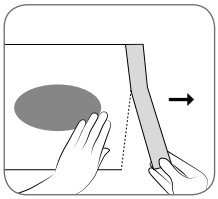
a) Peel the central layer “1”



b) Place the adhesive face down over the foam and remove side layers “1”



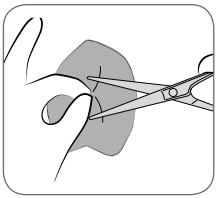
c) Peel top layer “2”



d) Detach handling bars along perforated lines

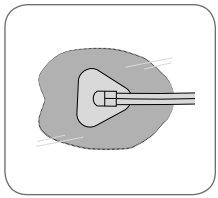
Film should extend 3–5 cm beyond wound margin to facilitate adequate seal.
Film should be securely anchored to periwound area to maintain an air tight seal.
Film can be cut into multiple pieces for easier handling, Make sure to retain a portion of the handling bars on each piece.

Step 3 – Cut hole in the film



Select an appropriate location over the dressed wound bed for the suction pad (FitPad) to be applied and pinch the Transparent Film over the area lifting slightly. Cut a small hole in the pinched area (approx. 1 cm diameter).

Step 4 – Attach the suction pad (FitPad)



Peel off the backing of the suction pad.

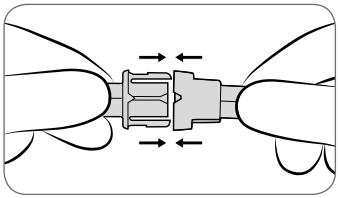
Center the suction pad over the previously cut hole in the dressed wound and apply by pressing firmly for adherence.

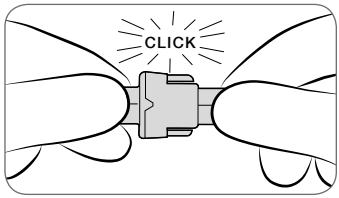
Pay attention to tubing positioning to allow for optimal flow: avoid placement over bony prominences.

Step 5 – Connect the dressing tubing to the pump tubing

Make sure both parts of the Quick-connector are aligned correctly as shown in the picture below.

Push the Quick-connector together until you hear a click.





Step 6 – Turn on the pump

Turn on the pump and select the prescribed therapy setting.
Check that the seal is secure around Transparent Film and suction pad.
Finished dressing should be firm to the touch. If there is concern of the tube creating pressure on the wound margins, utilize bridging technique.

Dressing application for incision management

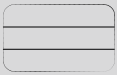
Incision site preparation

- Clean the application site per physician's orders.
- Pat the application site dry with sterile gauze.
- **Protect the periwound skin from** exposure to moisture and adhesive.

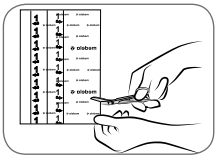
While the concomitant use of surgical drains is allowable with the Invia therapy system, the system must not be used as an outlet or reservoir to the drain. Surgical drains must be routed under the skin beyond the boundary of the dressing and function independently of the Invia NPWT System.

Dressing application

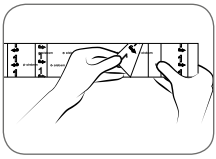
Select the appropriate dressing size according to the guidance below.

Description	Invia Foam Dressing Kit with FitPad			
Size	Small (200.8905)	Medium (200.8906)	Large (200.8907)	X-Large (200.8908)
Foam dimensions (Length x Width x thickness)	10 cm x 8 cm x 3 cm	19 cm x 12.5 cm x 3 cm	25 cm x 15 cm x 3 cm	60 cm x 30 cm x 1.5 cm
No of strips	2 strips of 5 cm width	2 strips of 6.2 cm width	3 strips of 7.5 cm width	6/12 strips of 5 cm width
Suggested cutting (for maximal total length of foam strips)				Film can be cut longitudinal or vertical
Total length of foam strips	16 cm (2 x 8 cm)	38 cm (2 x 19 cm)	75 cm (3 x 25 cm)	360 cm (6 x 60 cm) Or (12 x 30 cm)
Max length of incision	11 cm	33 cm	70 cm	….

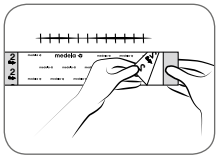
Step 1 – Protect peri-incisional skin



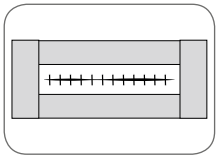
a) Cut a few strips 3 cm wide, from the Transparent Film. Make sure to retain a portion of the handling bars on each piece.



b) Peel the central layer "1"

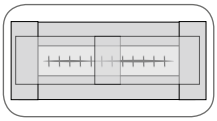


c) Place the adhesive face down over the skin and remove side layers "1". Remove top layer "2" and detack handling bar.



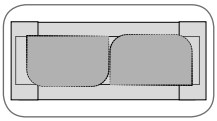
d) "Picture frame" the suture or staple line with the Transparent Film to protect intact skin approx. **3cm** on all sides and leave the suture line exposed.

Step 2 – Protect the surgical incision



Place a non-adherent contact layer over the entire length of incision, extending over the Transparent Film applied to protect the skin. Include at least 2.5 cm over either end of the incision.

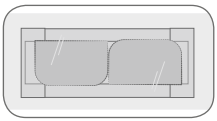
Step 3 – Apply the foam



Cut the foam into strips, minimum 5 cm wide. Cut enough strips to cover entire incision length and a least 2.5 cm over each end of the incision.
Place the foam strips along the entire length of the non-adherent contact layer. If multiple foam strips are used, ensure that the strips touch each other in order for negative pressure to be applied over the length of the incision.

☛ Do not allow the foam to touch the intact skin.

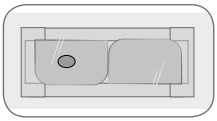
Step 4 – Apply Transparent Film

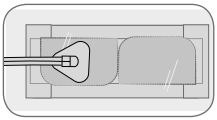


Cut the Transparent Film to allow for coverage of the foam strips and 3–5 cm contact with intact skin.
Apply Transparent Film over the full surface of foam, extending around intact skin. (Refer to step 1b and 1c for details)

☛ To avoid trauma to the periwound skin, do not pull or stretch Transparent Film over the foam during film application

Step 5 – Apply suction pad (FitPad)



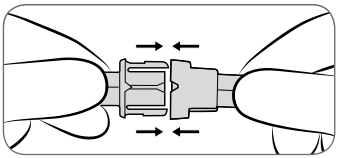


Select an appropriate location over the dressing for the suction pad (FitPad) to be applied and pinch the Transparent Film over the area lifting slightly.
Cut a small hole in the pinched area (approx. 1cm diameter).
Peel off the backing of the suction pad.
Center the suction pad over the previously cut hole in the dressed wound and apply by pressing firmly for adherence.

Step 6 – Connect the dressing tubing to the pump tubing

☛ Make sure both parts of the Quick-connector are aligned correctly as shown in the picture below.

☛ Push the Quick-connector together until you hear a click.



Step 7 – Turn on the pump

Turn on the pump and select the prescribed therapy setting. The recommended pressure level is -125mmHg at constant mode.
Check that the seal is secure around Transparent Film and suction pad.
Finished dressing should be firm to the touch.

Wound assessment

CAUTION
Patient monitoring: The patient should be monitored regularly according to the physician's instructions and local facility guidelines to check for patient comfort, therapy compliance and signs of infection.

WARNING
Objective indications or signs of a possible infection or complication must be addressed immediately (e.g. fever, pain, redness, increased warmth, swelling or purulent discharge).Non-observance can lead to considerable danger to the patient.

Observe the wound/periwound tissue and exudate for signs of infection or other complications. The most common signs of infection include redness, tenderness, fever, swelling, itching, increased warmth in the wound area, strong odor or purulent discharge. Additional symptoms include nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucous membranes, disorientation, high fever (>102° F, 38.8° C), refractory and/or orthostatic hypotension, or erythroderma (a sunburn-like rash). More serious complications of infection include pain, discomfort, fever, gangrene, toxic or septic shock. If more serious complications of infection occur, discontinue therapy and consult a healthcare professional immediately.

Dressing changes

- Dressings should be changed every 48–72 hours.
- In the event of heavy drainage, drainage with sediment or infected wounds, more frequent dressing changes may be needed.
- Check dressings regularly and monitor the wound to check for signs of infection. If there are any signs of systemic infection or advancing infection at the wound site, contact the treating physician immediately.

Dressing Removal

a. Turn the pump off.
b. Close the clamp on the dressing tubing.
c. Close the clamp on the pump tubing.
d. Disconnect pump tubing from dressing tubing by pressing on the sides of the Quick-connector.
e. Remove the Transparent Film from the skin by gently pulling parallel with the skin.
f. Remove the foam from the wound.

WARNING
Ensure the same number of foam pieces that were placed in the wound has been removed.

If dressing adheres to wound, apply normal saline into the dressing and wait for 15–30 minutes before gently removing the foam.

If the patient experiences discomfort during the dressing change, consider premedication, the use of non-adherent wound contact layer before foam placement, or managing the discomfort as prescribed by the treating physician.

g. Dispose of the dressing in accordance with local guidelines.
h. Prepare the wound for the next dressing as described under "Wound preparation".

Signs and symbols

This symbol indicates a prescription device. CAUTION: Federal US law restricts this device to sale by or on the order of a physician. (for US only).

This symbol indicates the temperature limitation for operation and storage.

This symbol indicates the manufacturer.

This symbol indicates that the device should not be used after the date shown.

This symbol indicates a CAUTION or WARNING associated with the device.

This symbol indicates manufacturer's batch code.

This symbol indicates a single use device. Do not reuse the device.

This symbol indicates the compliance with the essential requirements of the Council Directive 93/42/ EEC of 14 June 1993 concerning medical devices.

This symbol indicates the date of manufacture.

This symbol indicates the device is sterilized using ethylene oxide.

This symbol indicates to follow instructions for use.

This symbol indicates the humidity limitation for operation and storage.

This symbol indicates do not use the device if package is damaged.

This symbol indicates manufacturer's catalogue number.

This symbol indicates safety related tip.

This symbol indicates the atmospheric pressure limitation for operation and storage.

This symbol indicates number of items.