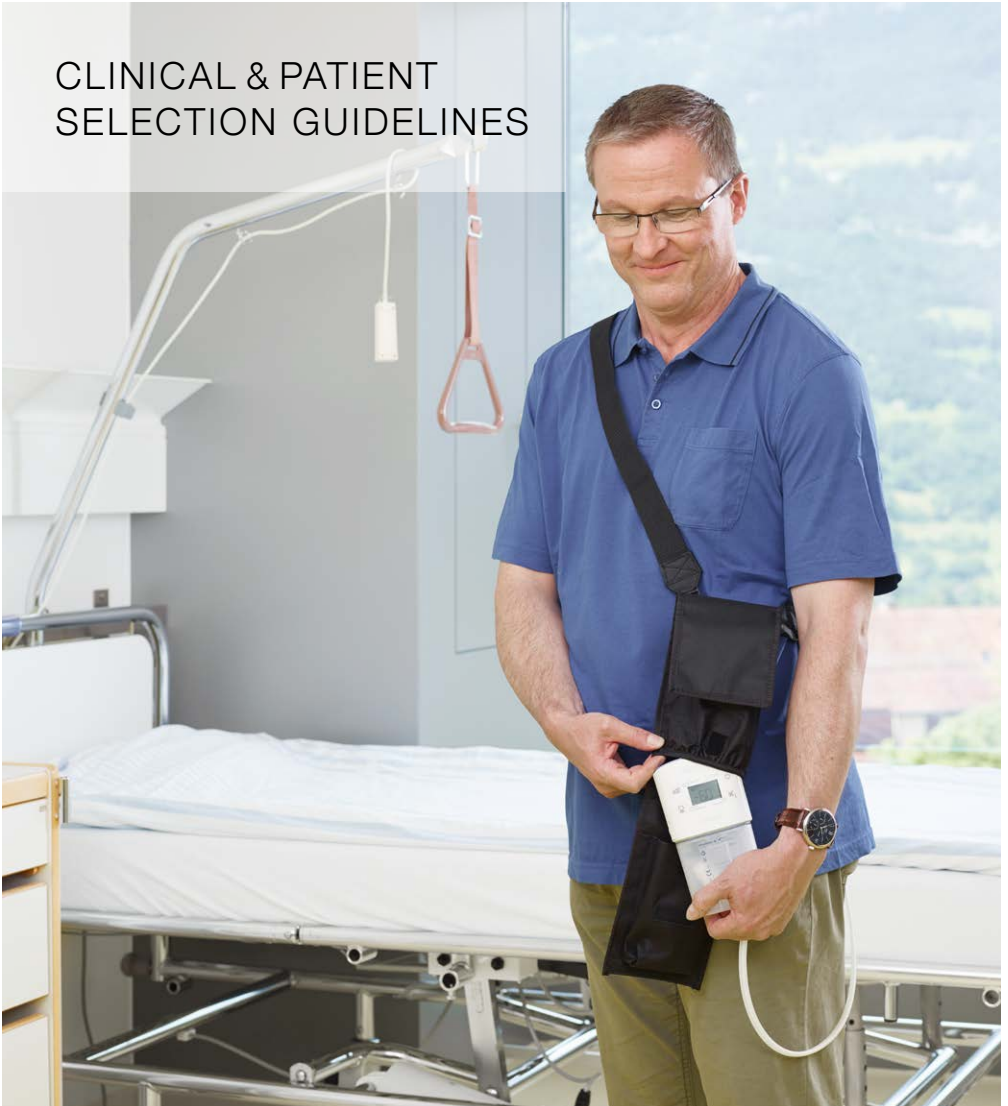


# Invia® Negative Pressure Wound Therapy (NPWT) System

## CLINICAL & PATIENT SELECTION GUIDELINES



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# INTRODUCTION, INDICATIONS, CONTRAINDICATIONS, WARNINGS AND CAUTIONS

## Negative Pressure Wound Therapy (NPWT)

Negative Pressure Wound Therapy (NPWT) is one of the most widely accepted advanced wound care treatment modalities for the management of acute and chronic wounds. NPWT refers to a system that consists of a wound dressing and a pump that continuously or intermittently applies controlled sub-atmospheric pressure to a wound to remove exudate and debris, thereby promoting enhanced wound healing.<sup>1</sup>

Clinical research supports that NPWT controls bacterial growth, reduces edema through the removal of excess fluid while maintaining a moist wound environment, may increase vascularity to the wound thereby optimizing tissue perfusion, and may increase the rate of cellular proliferation and granulation tissue formation.<sup>2, 3, 4, 5, 6, 7</sup> NPWT is indicated for both acute and chronic wounds which may include: diabetic foot ulcers, pressure injuries, partial-thickness burns, flaps, grafts.

The use of NPWT has been shown to be effective for many wound types, although the inappropriate use could cause pain and injury to the patient. Each wound and patient is unique; a thorough understanding of the current empirical data and the standards of practice surrounding NPWT will assist with clinical decision making. Medela Healthcare offers a choice of pumps and dressings to assist clinicians in all healthcare settings to support and manage the clinical needs for a wide variety of wounds with their patients.

These clinical guidelines refer to existing empirical research to assist with the use of the Invia Liberty™ & Invia Motion™ (NPWT) Systems and associated products. The safe and efficacious use of NPWT requires a qualified healthcare provider who is adequately trained in both wound care and NPWT. The Instructions for Use (IFU) for all the components in the Medela NPWT portfolio should be referred to prior to operating the Invia Liberty and the Invia Motion NPWT pumps and the Invia dressing kits.

As with any medical therapy please consult with the patient's attending physician for specific instructions regarding any treatment with NPWT.

Contact Medela Customer Service for help with product operation: United States: (877) 735-1626 or [info-healthcare@Medela.com](mailto:info-healthcare@Medela.com).

# Invia® NPWT Portfolio



- The main components of the Medela NPWT Portfolio are
  - Invia Liberty NPWT pump
  - Invia Motion NPWT pump
  - Invia Abdominal Dressing Kit
  - Invia Foam Dressing Kits with FitPad
  - Invia Gauze Dressing Kits with FitPad
  - Invia Silverlon NPWT Antimicrobial Wound Contact Dressing
  - Invia White Foam dressing



### **Invia® Liberty NPWT pump**

The lightweight (2.2lbs) Invia Liberty NPWT pump provides an adjustable negative pressure range from -40mmHg to -200mmHg and two therapy modes constant and intermittent, along with an electronic measuring and monitoring system. The pump can be used with either foam or gauze dressing kits.



### **Invia® Liberty carrying case**

The Invia carrying case allows the patient to be mobile with the pump and a 300 ml canister.



### **Invia® Liberty canisters 300 ml & 800 ml**

The Invia disposable canisters with solidifier collect exudate from the wound. They contain a bacterial filter and a carbon filter which assists with minimizing exudate odour.



### **Invia® Liberty canister tubing**

The Invia canister tubing has two lumens, the smaller one regulates the pressure while the larger one removes the fluid from the wound into the canister. The Quick-connector at the end of the canister tubing connects to the FitPad tubing.



### **Invia® Motion NPWT pump**

The lightweight (0.81 lbs) Invia Motion NPWT pump is a personal use pump which provides an adjustable negative pressure from -40mmHg to -175mmHg and two therapy modes, constant or intermittent. It can be used with foam or gauze dressings. The Invia Motion NPWT pump can be used in all healthcare settings.



### **Invia® Motion carrying case**

The carrying case for the Motion NPWT pump allows the patient to be mobile. It can be worn in multiple configurations. The carrying case is single use per patient and disposed of after treatment discontinues.



### **Invia® Motion 150ml canister/tubing set**

The Invia Motion canister/tubing set is an accessory of the Invia Motion NPWT System. It is intended to collect wound exudate and infectious materials. The Quick-connector at the end of the canister tubing connects to the FitPad tubing.



### **Invia® Foam Dressing Kit with FitPad**

The Invia foam is a reticulated open pore structure made from a flexible polyurethane hydrophobic material. The foam is available in a dressing kit with a FitPad and transparent film(s). The kits come in small, medium, large and extra large sizes.



### **Invia® Gauze Dressing Kit with FitPad**

The Invia gauze is an antimicrobial gauze, impregnated with 0.2 % Polyhexamethylene Biguanide (PHMB). The Invia gauze is presented in a dressing kit with a FitPad, sterile normal saline and transparent film(s). The kits come in medium and large sizes.



### **Invia® Abdominal Dressing Kit**

The Invia Abdominal Dressing Kit provides an effective solution for the management of open abdominal wounds with exposed viscera and organs.



### **Invia® Silverlon NPWT Antimicrobial Wound Contact Dressing**

This wound contact layer can be used with the Medela NPWT System. It provides a non-adherent, conformable, antimicrobial barrier and may help reduce infection when placed under reticulated foam, gauze, or other wound fillers. It is available in 2 sizes, 10 cm x 12 cm and 12 cm x 20 cm.



### **Invia® FitPad**

The Invia FitPad is intended to deliver and control pressure to the wound site and remove exudate from the wound into the disposable canister.



### **Invia® White Foam**

The Invia White Foam is a hydrophilic polyvinyl alcohol (PVA) foam to be used in conjunction with the Invia foam dressings or its components. The Invia White Foam is available in two sizes, small and large.



### **Invia® Transparent Film**

The Invia Transparent Film has an acrylic adhesive coating and a high moisture vapor transmission rate. The film is flexible allowing for an easy placement over the wound filler and onto the surrounding skin.



### **Invia® Y-connector**

The Invia Y-connector allows two wounds (of similar etiology), from the same patient, to receive simultaneous therapy utilizing one pump.



# Indications and Contraindications

The Medela Negative Pressure Wound Therapy (NPWT) system 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 Medela NPWT system 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 exudate via the application of Negative Pressure Wound Therapy.

## Indications <sup>8, 9, 11</sup>

- Acute or sub-acute wounds
- Chronic wounds
- Dehisced wounds
- Pressure ulcers
- Diabetic neuropathic ulcer
- Venous insufficiency ulcers
- Traumatic wounds
- Partial thickness burns
- Flaps and grafts
- Closed surgical incisions (not utilising white foam)

## Contraindications <sup>8, 9, 11</sup>

- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Malignancy in wound
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site of blood vessels or bypasses
- Exposed organs

## Warnings

Do not modify this equipment without authorization from the manufacturer. The safe and effective operation of this device requires specific instruction from a physician. Healthcare professionals who have been adequately trained in suction procedures, wound care, negative pressure wound therapy and in the use of aspirators or adequately trained lay users should use this equipment. Healthcare professionals are responsible to train lay users according to the patient instructions for use and explain all related safety information.

Incorrect use can cause pain and injury to the patient. Consult the indications for use, cautions and contraindications when using the Medela NPWT portfolio.

Failure to obtain consent and any additional instructions from the treating physician prior to use, may lead to death or injury of the patient.

A patient undergoing NPWT requires frequent supervision. Objective indications or signs of possible infection or complications must be addressed immediately (e.g. fever, pain, redness, increased warmth, swelling or purulent drainage). Monitor the device, wound, surrounding skin and patient status and comfort level frequently to ensure efficient, safe treatment and patient comfort.

Do not place the foam/gauze dressing directly on exposed blood vessels, organs, nerves, tendons, bones or ligaments. When using the Medela NPWT portfolio in close proximity to these structures a protective barrier, such as a non-adherent wound contact layer, must be used.

Serious or fatal injury can result from bone fragments or sharp edges (e.g. staples or hardware) that could puncture protective barriers, vessels or organs. The patient must be closely monitored for bleeding. If sudden or increased bleeding is observed, immediately stop use of the pump, apply pressure on wound dressing and seek immediate Emergency Medical Attention.

Should a spinal cord injury patient experience autonomic hyperreflexia, discontinue treatment with the Invia NPWT System and consult a physician immediately.

Never place the Invia Liberty NPWT pump in water or liquids. Clamp the drain and disconnect from the dressing prior to bathing or showering.

Consider the use of a protective barrier on skin that may come in contact with the tubing, especially in patients with fragile skin.

Do not use oxidizing agents, such as hydrochlorite solutions or hydrogen peroxide in the wound before applying a foam dressing.

Invia NPWT System instructions advise 24 hours therapy without interruption. If therapy is discontinued for more than 2 hours using foam or gauze, the dressing should be replaced and therapy restarted by a healthcare professional.

This device has not been studied with pediatric patients.

Clamp the drain and disconnect the Invia Liberty or Invia Motion NPWT pump prior to patient entering hyperbaric oxygen chamber (HBO) or Positron Emission Tomography (PET).

**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 (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.

**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, peri wound 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 sun-burn-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/gauze 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 bio absorbable. 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.

## Cautions

The following statements describe medical conditions that may require special care for the safe and effective use of the Invia Liberty and Invia Motion NPWT System.

- Patients at high risk for bleeding and hemorrhage, including patients experiencing active bleeding or difficult wound hemostasis.
- Patients taking anticoagulants or platelet aggregation inhibitors.
- Patients with a history of vascular anastomosis or friable, irradiated, sutured or infected blood vessels.
- 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 of the sympathetic nervous system), discontinue negative pressure wound therapy to help minimize sensory stimulation and seek immediate medical assistance.
- Patients with infected wound or osteomyelitis.
- Wounds that involve an enteric fistula.
- To minimize the risk of bradycardia, NPWT must not be placed in the proximity of the vagus nerve.
- Avoid circumferential dressing applications.
- The Negative Pressure Wound Therapy must be used 24 hours per day without interruption. If the pump is stopped for more than 2 hours, the dressing must be changed and therapy restarted.
- Consider the patient's size and weight when prescribing this device.
- Consider mode of therapy – intermittent versus continuous.

# PATIENT CONSIDERATIONS

## Goal of Negative Pressure Wound Therapy (NPWT)

NPWT can provide many clinical benefits for patients. Each patient and each wound will require different considerations when using NPWT and therefore have different outcomes. A clear concise treatment plan should be decided and documented with expected outcomes before commencing NPWT. These will provide the marker for considering discontinuation of therapy at the appropriate time.

# Patient selection

NPWT can be a safe and effective active wound treatment modality when used with select patients whose health status and local wound environment have been assessed and optimally prepared.

All of the patients’ physiologic needs must be addressed. This includes controlling or eliminating causative factors including but not limited to pressure, shear, moisture, circulatory impairment and neuropathy. Providing systemic support to reduce existing and potential co-factors includes providing nutrition and fluid support, and effective pain management. This also includes interventions or measures to control systemic conditions affecting wound healing such as diabetes and immunosuppression. Psychological support is also needed to encourage behaviors that will support wound healing.<sup>11</sup>

It is also important to have an accurate and full diagnosis of not only the patient’s wound, but also any comorbid conditions which may affect the patient’s wound healing process. In addition, patients should be assessed for excessive motion at the wound site, systematic hypoxia, dehydration or blood volume deficiency. The table below is a guide from the World Union of Wound Healing Societies (WUWHS) 2008<sup>13</sup> to assist clinicians with their decision making when using NPWT.

Table 1

Wound factors	Patient factors
<ul style="list-style-type: none"><li>– Wound has good blood supply</li><li>– Wound has healthy, granular bed</li><li>– Wound has been freshly debrided (as recommended*)</li><li>– Wound produces high levels of exudate</li><li>– Wound is greater than 2 cm wide</li></ul>	<ul style="list-style-type: none"><li>– Patient has been maximally medically stabilized (eg nutrition, blood pressure blood glucose, fluid balance, infection)</li><li>– Patient has few or well-controlled comorbidities</li><li>– Patient is comfortable (eg not in pain)</li><li>– Patient is adherent with therapy</li></ul>



In order to maximize the treatment benefits with a NPWT System, clinicians should review the indications, contraindications, warnings, and precautions associated with the therapy and evaluate patients for the following:

### **Nutrition**

Adequate nutrition is essential for wound healing. Without adequate nutrition the patient will be unable to heal, regardless of whether or not NPWT is initiated. Supplementation of nutrition (if required) should be considered to assist the patient with wound healing. The Academy of Nutrition and Dietetics (Academy) and the American Society for Parenteral and Enteral Nutrition (ASPEN), developed a consensus for the criteria for a diagnosis of malnutrition. The criteria include: insufficient energy intake, weight loss, loss of muscle mass, loss of subcutaneous fat, localized or generalized fluid accumulation that may sometimes mask weight loss, and diminished functional status as measured by handgrip strength. A full nutritional assessment which may include: physical appearance, muscle and fat wasting, swallow function, appetite and affect and biochemical data which may include serum albumin & pre albumin levels, anemia profile, transferrin levels, and hydration status is an example of a full nutritional assessment.<sup>14</sup>

### **Circulation**

Adequate circulation is essential to the healing process as it allows for transport of oxygen, cytokines and other growth factors needed to move the wound through the phases of healing<sup>15</sup>. Use of NPWT over ischemic or necrotic tissue such as an ischemic foot may aggravate the condition. If there is doubt about viability of the tissue around or within the wound, measures should be taken to ascertain the perfusion and/or oxygen supply and assess the condition of pulses, capillary return of pulses, capillary return, transcutaneous PO<sub>2</sub>, arteriogram, etc. Application of NPWT may decrease the blood flow to the immediate area, therefore, lower pressures on wounds with compromised vascularity or perfusion is recommended.<sup>2</sup>

### **Debridement**

Wounds must be debrided of all devitalized tissue prior to placement of any NPWT System. This debridement may include bone if osteomyelitis is present. NPWT is contraindicated when necrotic tissue with eschar is present; however, soft stringy slough is not a contraindication, but may slow the healing progression of the wound.<sup>6, 12, 16</sup>

### **Infection**

For better results, the wound should be free from infection in both underlying tissue and bone. NPWT is contraindicated for wounds with untreated osteomyelitis. If signs of infection are present, topical or pharmacologic therapy and or further debridement should be considered. NPWT may be used as an adjunct

therapy for infected wounds, but should not be considered as the primary treatment. NPWT has been shown in studies to be effective in reducing the bacterial load, but has not been proven to be an adequate treatment for infection by itself.<sup>2, 16</sup>

### **Environment optimization**

Depending on the pathology of the wound to be treated, consider the following measures prior to starting NPWT or during initiation of therapy.

- Offloading pressure
- Control of moisture
- Reduction of shear or friction
- Prevent pressure from device tubes

## Wound assessment and monitoring

A thorough baseline wound assessment should be done when the wound is initially observed. The baseline assessment will determine the treatment options and the patient's care plan. The baseline assessment must include all aspects of the patient's care, especially factors that affect wound healing. Failure to complete a comprehensive baseline assessment will compromise the care plan and the patient's care. A follow-up wound assessment with every dressing change should be done to evaluate the healing progress and to refer to the patient's care plan and adjusted as required.

Factors that may be included in a wound assessment <sup>17</sup>:

- Etiology of the wound
- Location of the wound
- Measurement in centimeters (length x width x depth) and any undermining or tunneling
- Edges of the wound bed (attached, not attached, rolled)
- Appearance of the wound base (color, necrotic tissue, exposed bone, etc)
- Exudate (amount, consistency, and color)
- Odor from the wound
- Appearance of granulation tissue
- Appearance of epithelial tissue
- Peri wound skin condition
- Pain experienced at any time

Frequent assessment of the wound/periwound tissue and exudate should be undertaken for signs of infection or other complications. Infected wounds should be monitored more closely and may require more frequent dressing changes than non-infected wounds. Most common local signs of infection include redness, tenderness, fever, swelling, itching, increased warmth in the wound area, strong odor or purulent discharge.

Additional symptoms of a systemic infection may include nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucous membranes, disorientation, high fever ( $> 102^{\circ}\text{F}$ ,  $38.8^{\circ}\text{C}$ ), refractory and/or orthostatic hypotension, orthostatic, or hypotension, or erythredema (a sun-burn-like rash). More serious complications of infection include pain, discomfort, fever, gangrene, toxic shock, or septic shock. **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.**

Place the Medela NPWT device at a convenient location that allows for periodic monitoring, according to facility policy. Frequent monitoring and recording of the volume and character of exudate is recommended. The wound filler should be monitored to ensure that a seal is still being maintained along with the correct operation of the pump.

### Discomfort with NPWT

Occasionally, patients may describe some discomfort with therapy or upon dressing changes. As pain is very subjective, it is important to understand the type, level and duration of the patient's discomfort. Most institutions and agencies have a validated tool to assess and document the patient's discomfort during therapy.

The following therapeutic interventions may be considered to help reduce patient discomfort:

- Educate the patient about the therapy and possible discomfort prior to application.
- Closely monitor patient's pain level and initiate comfort measures (relaxation techniques), or administer analgesic to appropriately alleviate discomfort.
- If the discomfort is at the periwound area, check that the foam or gauze dressing is not in direct contact with intact skin.
- Reduce the target negative pressure by  $-10$  mmHg until discomfort subsides. Then increase slowly to the prescribed level of therapy if the patient is able to tolerate.
- Assess for signs and symptoms of wound infection.
- The use of a wound contact layer prior to application of the foam/gauze may also decrease pain during the next dressing change.
- Consider changing wound filler from foam to gauze
- Increase the frequency of dressing changes for dressing adherence
- Decrease dressing changes according to patient tolerance
- Instill normal saline into the wound dressing prior to dressing removal, leave to soak for approximately 15–30 minutes
- Consider instilling topical lidocaine, 4 % topical, into the wound dressing prior to dressing removal<sup>2</sup> (This must be ordered by the prescriber/physician)
- Re-evaluate after a comfort measure has been implemented and adjust plan of care as required.

# THERAPY RECOMMENDATIONS

## Duration of therapy

Negative Pressure Wound Therapy (NPWT) is recommended to be applied for 24 hours a day without interruption. If therapy is discontinued for more than 2 hours, the dressing should be replaced and therapy restarted by a healthcare professional. The length of treatment will vary from patient to patient.

## Pressure settings

The standard pressure of -125 mmHg has been used for more than 15 years with a variety of patients and their wounds. As NPWT has become standard of practice in many clinical settings a range anywhere from -40 to -175 mmHg is currently used.<sup>2, 18, 19</sup>

The pressure level (mmHg) may be increased for large amounts of exudate, to secure a seal in a large wound area or decreased for pain, ischemia, or based on the wound filler. The pressure level is set according to the prescribing clinician's or provider's instructions, based on the indication, the condition of the wound, the objectives of treatment and which wound dressing is being used. For general guidance, suggested pressure settings are:

- Foam dressings from -75 mmHg to -125 mmHg
- Gauze dressings from -60 mmHg to -80 mmHg
- White Foam dressings from -80 mmHg to -150 mmHg

## Therapy modes

### Constant or intermittent

NPWT usually has two therapy modes available, constant or intermittent. The standard setting for NPWT is usually constant therapy. Constant therapy means that negative pressure is continuously being delivered to the wound. Intermittent therapy stops the therapy for a specific time and then resumes therapy and continually alternates between a pre-set time on and a pre-set time off (i.e. on for 5 minutes and off for 2 minutes). Most NPWT devices are programmable for a timed duration. The Invia Liberty NPWT pump has a programmable range anywhere from 8 minutes on and 8 minutes off. The Invia Motion NPWT pump is pre set to deliver 5 minutes of therapy and 2 minutes without therapy. 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, undermining or sinuses
- Skin grafts
- Moderate to heavy levels of exudate
- Painful wounds
- Wounds that are difficult to maintain a seal

It is important to keep in mind that intermittent therapy can also be associated with negative effects such as heightened pain, sleep disturbance, and sub-optimal exudate management. The on/off regime should be decided by the clinician when using the Invia Liberty NPWT pump. The condition of the wound will determine the optimal regime. The therapy mode must be determined by the prescriber/provider.<sup>2, 6, 16, 19, 20</sup>

## Dressing selection

The Invia NPWT System utilizes both foam and gauze dressings as the wound filler for NPWT. The empirical data shows no difference in healing rates between the two wound fillers and there is no difference in the wound contraction or stimulation of blood flow<sup>7</sup>. Foam dressings are usually made of a polyurethane hydrophobic foam (Charcoal coloured foam), or polyvinyl alcohol foam (White foam) which allows the distribution of pressure across the wound surface and to allow fluid and exudate through the negative pressure system. The Invia White Foam is a hydrophilic, enormously absorbent foam. This means it is ideal for the effective removal of wound exudate and tissue fragments Gauze is sometimes utilised for larger wounds for the ease of application, to decrease pain upon dressing removal, to decrease trauma of new granulation tissue and over sensitive structures. The choice of dressing must be determined by the prescriber/provider. Table <sup>2, 19</sup> below gives some examples:

Table 2

Examples of Wound Characteristics Matched with Wound filler						
Wound Characteristics	NPWT Open-Cell Foam	NPWT Higher-Density, Moist, Open-Cell Foam	Gauze-Based Filler	Contact Layer (Under Filler)	Antibacterial Layer Under Filler or Silver-Coated Cell Foam	Irrigation with Open-Cell Foam
Deep but visible wound cavity	x		x			
Wound cavity with tunnels or deep undermining		x	x			
Infected wound					x	x
Wound with exposed structures		x		x		
Skin graft bolster	x			x		
Fragile wounds (bleeding potential, friable tissue)		x		x		

## Wound contact layer

A wound contact layer described while utilizing NPWT is a non-adherent layer between the wound filler and the wound bed. There are many contact layers available. The main reason to use a contact layer is to prevent tissue in-growth while utilizing a foam filler, to decrease pain, to protect structures, or to add an antimicrobial layer. A wound contact layer may also be used to protect sutures, staples, bone, and tendon and also around a piece of foam if placed into an area of tunneling or undermining. The use of a wound contact layer must be determined by the prescriber. Additionally, when there is a concern of the foam fraying in the wound bed, a contact layer may be utilized. <sup>2, 16, 19</sup>

## Frequency of dressing change

Invia NPWT Dressings, Transparent Film, FitPad or drain and any wound contact layer should be changed every 48–72 hours. 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 changes should be performed as per clinicians/licensed provider instructions and based on the assessment at each subsequent dressing change.

# Discontinuing NPWT

The decision to discontinue NPWT is based on the patients progress and the goal of therapy. Healing times are dependent on the etiology and pathology of the wound as well as the patient's health status and co-morbidities. <sup>12, 16, 29</sup>

Possible criteria for the discontinuation of NPWT are as follows<sup>21</sup>

- Achieved the desired goals of therapy
- The wound bed is sufficiently prepared with granulation tissue
  - Decrease in wound volume (width, depth, tunneling, undermining)
  - The wound bed is prepared for a flap or a graft, or optimized for surgical closure
- Exudate volumes have reduced to desired levels
- Complications develop:
  - Excessive bleeding
  - Inability to obtain an adequate seal
- Failure to improve:
  - Deterioration of wound
  - Worsening infection
  - Significant periwound maceration
  - No improvement of wound
- Poor patient compliance
- Patient cannot tolerate therapy



# WOUND TYPES

## Pressure injury

The following are the definitions from the National Pressure Ulcer Advisory Panel, April 2016<sup>22</sup>:

“A pressure injury is localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.”

NPWT is indicated for Stage 3 and Stage 4 pressure injuries

### **Stage 3 pressure injury: Full-thickness skin loss**

“Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.”

### **Stage 4 pressure injury: Full-thickness skin and tissue loss**

“Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.”

### General NPWT Indications for pressure injuries

- Full-thickness skin loss (Category/Stage 3 or Category/Stage 4)
- Inadequate granulation tissue
- Heavy exudate
- Pressure Injury with tunneling or undermining
- Preparation for a flap/graft placement
- Non-healing pressure injury

### Objectives for using NPWT with a pressure injury<sup>6, 12</sup>

- To promote granulation tissue formation
- Remove edema
- Remove exudate
- Prepare the wound bed for a possible surgical procedure

### Application

Due to the anatomical location of the pressure injury it may be necessary to position the Invia FitPad away from the wound to avoid any undue additional pressure. A bridging technique should be considered. Any exposed bones should be protected before applying a foam/gauze dressing. The patient may also require a pressure relieving device, and regular repositioning will be required.<sup>23</sup>

### Application with pressure injuries

With some pressure injuries tunnels or areas of undermining maybe present as mentioned in the National Pressure Ulcer Advisory Panel (NPUAP) recent publications <http://www.npuap.org/resources/educational-and-clinical-resources/npuap-pressure-injury-stages/>

If tunnelling is present, consider using the Invia White Foam in this area and Invia charcoal-coloured Foam in the rest of the wound cavity. The tunnel area should be accurately documented to its position within the wound, measure and recorded. The Invia White Foam should be cut slightly longer than the depth of the tunnel. It should be cut to fit into the tunnel area. The Invia White Foam should be inserted into the tunnel and withdrawn slightly. Make sure that the end of the Invia White Foam can be clearly seen protruding from the opening of the tunnel. If the rest of the wound is a cavity then consider filling the cavity with the Invia charcoal coloured Foam. The Invia White Foam needs to be in contact with the Invia charcoal coloured Foam. Once the wound is filled then cover with transparent film. Cut a hole in the film 1cm x 1cm. Apply the Invia FitPad over the cut hole.

# Lower extremity ulcers

Lower extremity ulcers (diabetic, venous, and arterial) present a major burden to the healthcare system. In the United States venous ulcers are the most common lower extremity ulcer, said to affect 1 % of the population. Both arterial and diabetic ulcers are on the rise in the US due to uncontrolled diabetes, at least 8 % of the population is affected by diabetes. Additionally, in Canada, the incidence of diabetes increased 230 % from 1998 to 2009. Diabetic Foot Ulcers (DFU) precede amputations 85 % of the time. The empirical data supports the use of NPWT for lower extremity ulcers. <sup>3, 12, 17, 18, 19</sup>

**Diabetic** lower extremity ulcers that may be caused by three monumental pathways: peripheral neuropathy, structural foot problems and minor trauma.

**Venous** ulcers can present due to chronic venous insufficiency, leg related manifestations of venous hypertension and functional abnormalities of the venous system (i.e. lower extremity venous disease)

**Arterial** ulcers can present in an ischemic limb due to chronic occlusion or compromised or reduced vascularity, which typically involve the toes or distal foot. Ischemic ulcers may also be caused by trauma.

## Objectives for using NPWT with lower extremity ulcers

- To manage exudate
- To promote granulation tissue formation
- To remove edema

## Considerations for NPWT and lower extremity ulcers<sup>24</sup>

- Ischemia
  - NPWT should be carefully used in diabetic wounds with chronic ischemia, close monitoring of NPWT is recommended. A lower pressure may be considered and a positive palpable foot pulse should be present. The patient should have a less than 2 second capillary refill
- Neuropathy
  - Is a contributor to diabetic foot ulcers
  - Requires proper offloading
- Infection
  - Untreated osteomyelitis is a contra indication for NPWT. If treatment for osteomyelitis has commenced, then NPWT can be considered

## Application

- Due to the anatomical location of the wound it may be necessary to position the Invia FitPad away from the wound to avoid any undue additional pressure. A bridging technique should be considered. Any exposed bones should be protected before applying a foam dressing.

# Diabetic Foot Ulcers (DFU) and foot wounds

There are a number of publications showing the efficacy of NPWT with Diabetic Foot Ulcers (DFU). This efficacy had been shown with a variety of outcomes, such as faster wound healing, faster granulation tissue formation, fewer secondary amputations and fewer infections.<sup>25, 26</sup> The correct application and maintenance of a good seal will help to ensure a favourable outcome with NPWT.

## Objectives for using NPWT with a diabetic foot ulcer (DFU)

- To promote granulation tissue formation
- To prepare the wound bed for surgery
- To manage edema and prevent maceration of the peri wound area
- To prevent secondary complications

## Considerations for NPWT and diabetic foot ulcers <sup>25, 26, 27, 28</sup>

- Select dressings principally on the basis of exudate control, comfort and cost
- Debridement may be required. Consider debridement prior to application of NPWT
- NPWT is contraindicated for wounds with eschar and does not perform as well with devitalized tissue in the wound bed. Remove slough, eschar and surrounding callus
- Proper offloading has significant effects on healing of diabetic foot ulcers
- Controlling blood sugar needs to be considered to promote effective wound healing
- Close monitoring of the patient and the wound is recommended while receiving NPWT

## Application

Due to the anatomical location of the DFU it may be necessary to position the Invia FitPad away from the wound to avoid any undue additional pressure. The patient may also require an off loading shoe or boot. In this case a bridging technique should be considered where the Invia FitPad and tubing are not compromised by the off loading device. Any exposed bones should be protected before applying a foam/gauze dressing. Avoid any circumferential application with the film around toes or foot.

# Venous ulcers

Venous ulcers are typically seen in the area above the ankle and below the knee. Compression therapy is accepted as the gold standard for venous insufficiency. If compression therapy is not effective, NPWT may be used to increase the quality of the wound bed by decreasing edema and fibrotic tissue. NPWT may also assist with preparing the venous ulcer for a skin graft.

## Objectives for using NPWT with a venous ulcer

- To prepare the ulcer for a skin graft placement
- To bolster a skin graft on a venous leg ulcer
- To manage excessive exudate

## Considerations for NPWT & venous ulcers<sup>29</sup>:

- The periwound area should be appropriate for the application of film
- A circumferential dressing technique should be avoided
- There should be a palpable foot pulse
- Capillary refill should be less than 2 seconds
- Monitor closely to ensure that therapy is tolerated
- Consider using a gauze dressing if pain is present during dressing changes

## Application

Due to the anatomical location of the venous ulcer it may be necessary to position the Invia FitPad away from the wound to avoid any undue additional pressure. The patient may also require compression bandaging. In this case a bridging technique should be considered where the Invia FitPad and tubing are not compromised by compression bandages. Avoid circumferential application with the film around the legs.

# Arterial ulcers

Arterial ulceration is due to a reduced arterial blood supply to the lower limb. The most common cause is atherosclerotic disease of the medium and large sized arteries. The reduction in arterial blood supply results in tissue hypoxia and tissue damage. Arterial ulceration often occurs after seemingly trivial trauma or as the result of localized pressure.

The treatment for acute arterial insufficiency is primarily medical and includes the use of drugs to decrease the risk of thrombus formation. Non-medical treatments in the form of moderate exercise, such as walking, is also important to help reduce the progression of the disease.<sup>30</sup>

## Objectives for using NPWT with an arterial ulcer

- To prevent amputation
- To prepare for surgical closure

## Considerations for NPWT & arterial ulcers<sup>29</sup>

- For acute limb ischaemic, NPWT is not an optimal choice. Revascularization should be achieved first
- Close monitoring of the patient and the wound is recommended whilst receiving NPWT
- NPWT should be used cautiously with patients who have arterial ulcers after other modalities have failed
- The amount of negative pressure applied may have to be adjusted according to the patients pain reaction

## Application

Due to the anatomical location of the arterial ulcer it may be necessary to position the Invia FitPad away from the wound to avoid any undue additional pressure. In this case a bridging technique should be considered where the Invia FitPad and tubing are not compromising the rest of the limb. Avoid circumferential application with the film around the toes.

# Sternal wounds

Infection of a sternotomy wound is a potentially devastating and sometimes lethal complication following cardiac surgery. Although the incidence of post cardiectomy mediastinitis rate has been variously reported as between 0.8 %–5 %, the mortality rate varies anywhere between 19 %–29 % in different series of adult cardiac surgical patients.<sup>31</sup>

NPWT has been used very successfully with dehiscence sternal wounds and deep sternal wound infections. The advantages of NPWT in this instance is that it can stabilize the chest wall and allow for earlier extubation, remove excess fluid and reduce edema, shorten time to sterilization of the wound, reduce hospital stay, can be cost effective and improve early and long-term survival<sup>29</sup>.

There can be some challenges for the clinician when dealing with an open chest, as vital organs may be exposed. Only experienced clinicians should apply NPWT to exposed sternal wounds.

## Objectives for using NPWT with a sternal wound<sup>31</sup>

- To stabilize the chest wall, optimize respiratory function and allow patient mobility
- To prepare the wound area for further surgery
- To promote wound contraction
- To promote granulation tissue formation
- To manage exudate

## Considerations for NPWT & sternal wounds<sup>32</sup>

- If exposed structures are present, consider using surrounding tissue or fascia to protect these structures before inserting a foam or gauze dressing. If this is not possible, a wound contact layer should be considered.
- A physician should assess the patient prior to application
- Sometimes sternal wires are removed prior to application of NPWT

## Application

Due to the anatomical location of the sternal incision it may be necessary to position the Invia FitPad away from the wound to avoid any undue additional pressure. This can be positioned on a separate relocation site adjacent to the wound. All peri wound skin requires to have film placed on it first before applying any bridging pieces of foam or supporting foam for the Invia FitPad.

# Trauma wounds

Traumatic wounds can leave areas of tissue and bone loss along with unstable fractures, extensive bleeding vessels, unexpected amputations and can sometimes lead to death. Traumatic wounds can often pose clinicians a challenge when applying NPWT due to the anatomical location of the wound, the amount of tissue loss and any external fixation. Stabilization of the wound and any fractures along with minimizing the risk of infection are important factors to consider. NPWT can be advantageous to use with certain traumatic wounds.

A common goal in the use of NPWT, especially in patients with significant soft tissue traumatic defects, is to use NPWT to descend the reconstructive ladder, that is, to progress a wound from a complex wound which may require complex surgical closure (such as a microsurgical free flap) to a smaller and simpler wound which may be adequately managed with a simpler procedure (such as a split-thickness skin graft [STSG]).<sup>34, 35, 36</sup>

## Objectives for using NPWT with trauma wounds

- Minimize the risk of infection
- Manage exudate
- Optimize the wound bed, prior to further surgery
- Promote granulation tissue formation
- Remove edema

## Considerations for using NPWT with trauma wounds

- All exposed vasculature should be protected before applying a foam or gauze dressing
- Any wounds with external hardware may require additional attention to achieve a seal

## Application

Additional dressing components may be required to achieve a seal in difficult anatomical areas. An antimicrobial dressing may be considered for those traumatic wounds at risk of infection.



## Orthopedic wounds

Over the past 5 years, patients with open fractures have shown a significant outcome with the use of NPWT.<sup>35, 36</sup> Maintaining an effective seal with NPWT when fixators are present can be quite a challenge. Time spent preparing the wound, the surrounding area and all materials required will help to ensure a leak free dressing and therefore effective delivery of NPWT. Internal hardware can sometimes be a source of a wound dehiscence. This can either be removed or left in place and NPWT can be used as a useful adjunct.

### Objectives for using NPWT with an orthopedic wound<sup>36, 37, 38</sup>

- To remove edema
- To provide temporary wound cover
- To increase blood flow to the area
- To promote granulation tissue formation
- To secure muscle flaps or grafts

### Considerations for using NPWT with an orthopaedic wound

- NPWT can often be used as a bridging between surgical debridements for open fractures.<sup>37</sup>
- The presence of orthopedic hardware in or around the wound such as pins, rods, or plates is not a contraindication for use with the Invia Medela System. NPWT has been used to form granulation tissue in these types of wounds.<sup>12</sup> Following placement of the external fixator, the foam/gauze dressing can be directly applied to the wound. Transparent film, gauze, ostomy barrier paste or strips, can be placed underneath the fixator or wrapped around the pins to form an airtight seal.<sup>12</sup>

### Application

Due to the anatomical location of the wound and the presence of fixators or hardware it may be necessary to position the Invia FitPad away from the wound to avoid any undue additional pressure. In this case a bridging technique should be considered.

# Abdominal wounds

Abdominal wounds can sometimes occur after surgery, some from a dehiscence and others because it is not possible to close the abdomen due to infection or edema. Leaving abdomens open can improve patient's survival, although a temporary abdominal closure system is often required.<sup>2</sup>

For exposed bowel, intestines and organs a specialized` abdominal` dressing is normally required to be used with NPWT.

For an abdominal wound with no exposure of intestines or organs, traditional NPWT can be considered. Great care should be exercised if recently sutured vessels are present. Vulnerable structures may require to be covered with surrounding fascia, tissue or wound contact layers.

## Objectives for using NPWT with an abdominal wound

- Promote granulation tissue formation
- Remove edema and exudate
- Promote contraction of the wound
- Minimize risk of infection

## Considerations for using NPWT with an abdominal wound<sup>39</sup>

- A specialized dressing for eviscerated intestines should be used
- The presence of an enteric fistula requires careful application techniques when using NPWT

## Application

Traditional NPWT can be applied to abdominal wounds. A full assessment of the wound is advised to avoid any contact of foam with intestines or friable vessels. Consider the use of a wound contact layer if required.

## Dehisced wounds

After surgery some closed wounds can dehisce and become open wounds. This can occur due to a number of factors. Once these dehisced wounds are open they usually heal by secondary intention.

NPWT can be applied to dehisced wounds to help facilitate this intention. Exposed bones should be protected and exposed organs protected with surrounding fascia or wound contact layers.

### Objectives for using NPWT with a dehisced wound

- Promote granulation tissue formation
- Remove edema and exudate
- Promote contraction of the wound
- Minimize risk of infection
- Allow the patient to mobilize

### Considerations for using NPWT with a dehisced wound

- Any underlying infection that may have contributed to the wound dehiscence should be addressed. Any existing hardware may have to be removed prior to commencing NPWT.
- Any underlying hardware or prosthesis maybe a source of infection and wound breakdown. This should be regularly assessed.

### Application

Due to the anatomical location of the wound it may be necessary to position the Invia FitPad away from the wound to avoid any undue additional pressure. In this case a bridging technique should be considered or a mushroom technique. Please refer to the chapter on how to dress wounds smaller than the size of the Invia FitPad.

If using the Invia WhiteFoam, this should be placed over the skin graft including the edges of the graft. Transparent film is applied over this area and a hole cut into the film, 1cm x 1cm. The Invia FitPad is then applied over the cut hole. NPWT is then commenced at a lower pressure. ( Depending on the area size the charcoal coloured foam can be added over the white foam to assist with fluid removal).

# Closed Surgical Incisions

NPWT has been successfully applied to STSG (split thickness skin grafts) and FTSG (full thickness skin grafts) to aid with revascularization and 'take' of the graft. NPWT has also been used with composite grafts.

The usual process for using NPWT with skin grafts is preparation of the wound bed, placement of the graft then the re application of NPWT over the graft.

## Objectives for using NPWT with closed surgical incisions

- To prevent surgical site complications such as
- Surgical Site Infections (SSI)
- Seromas
- Oedema
- Wound dehiscence

## Considerations for NPWT and closed surgical incisions

- 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. When used on closed surgical incisions, the Invia NPWT system 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 exudate via the application of Negative Pressure Wound Therapy

## Application

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 every 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 haemostasis of the incision
- Cellulitis of the incision area

# Skin grafts

NPWT has been successfully applied to STSG (split thickness skin grafts) and FTSG (full thickness skin grafts) to aid with revascularization and 'take' of the graft. NPWT has also been used with composite grafts.<sup>40</sup>

The usual process for using NPWT with skin grafts is preparation of the wound bed, placement of the graft then the re application of NPWT over the graft.

## Objectives for using NPWT with a skin graft

- To improve the take rate of the skin graft
- To prevent the loss of skin graft in the at risk patients
- To stabilize the graft and promote revascularization
- To minimize seroma formation
- To allow mobilization of the patient with a well bolstered graft

## Considerations for NPWT and skin grafts<sup>40, 41, 42</sup>

- Do not apply foam or gauze directly on top of the graft, use a wound contact layer over the entire graft first and then apply foam or gauze over this
- The amount of negative pressure delivered is usually lowered when applied to a skin graft as the goals of therapy are different from other wound types
- The entire dressing is normally left undisturbed for a period of 5 to 7 days
- Once the graft has 'taken', NPWT is usually discontinued

## Application

The graft area should be covered with a non adherent wound contact layer beyond the edges of the graft (at least 2cm). The NPWT dressing, foam or gauze, should be applied over the wound contact layer. Transparent film is then applied over this area and a hole cut into the film, 1cm x 1cm. The Invia FitPad is then applied over the cut hole. NPWT is then commenced at a lower pressure. If using the Invia WhiteFoam, this should be placed over the skin graft including the edges of the graft. Transparent film is applied over this area and a hole cut into the film, 1cm x 1cm. The Invia FitPad is then applied over the cut hole. NPWT is then commenced at a lower pressure. ( Depending on the area size the charcoal coloured foam can be added over the white foam to assist with fluid removal).

# INVIA® NPWT SYSTEM

## APPLICATION GUIDES

### Prior to application

- Verify the physician/licensed providers order which will include the prescribed level of negative pressure described in mmHg, constant or intermittent therapy, gauze or foam dressing, and the frequency of dressing change.
- Explain procedure to patient/caregiver.
- If ordered, initiate patient comfort measures prior to dressing change.
- Use universal precautions and clean (sterile when appropriate) dressing change technique per facility protocol.
- Position patient to allow maximum exposure of wound.
- Assess the wound and periwound skin per facility protocol.
- Wounds should be debrided of necrotic tissue with eschar prior to placement of any NPWT System.

### Dressing changes

The following should be considered at every dressing change

- Wound assessment: measurements (L x W x D), drainage amount and consistency, appearance of wound bed, periwound skin, wound edges, odor, and pain.
- Re-evaluate the wound and the treatment modality with each dressing change.
- Cover any areas of wound that need protection (i.e., bone, tendon) with a wound contact layer.
- Ensure any nonviable tissue (eschar, hard slough) has been debrided from the wound and is cleansed per facility protocol.
- Never tightly pack a wound with either gauze or foam. Over packing can result in impaired wound healing, tissue damage and vasoconstriction.
- Record the number of pieces of either gauze/foam placed in the wound.
- Date and time the dressing change.

# Invia® Foam Dressing with FitPad application guide



## Dressing Application Guide

Invia® Foam Dressing Kit with FitPad



1. Thoroughly clean and debride the wound. Apply skin prep to protect the peri-wound skin.



2. If required, apply a non-adherent contact layer prior to placing the foam into the wound.



3. Cut the foam to fit the size and shape of the wound. Do not cut directly over the wound.



4. Rub the edges of the foam to remove any loose particles.



5. Place the foam into the wound cavity. Do not tightly pack or force foam into areas of the wound. Do not allow the foam to overlap onto intact skin.



6. Apply transparent film. Partially peel back one side of layer 1 and place the adhesive side down. Remove the remaining side of layer 1.



7. Now remove the transparent backing layer labeled 2.



8. Remove the perforated silver colored tab on the side. The film should extend 3–5 cm beyond the wound margin to facilitate adequate seal.



9. Select appropriate location for the suction pad (FitPad) to be applied. Pinch the film and cut a small hole (approx. 1 cm).



10. Peel the backing off the FitPad to expose the adhesive.



11. Place the FitPad centered over the previously cut hole in the dressing. Press firmly for adherence.



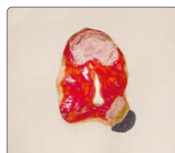
12. Attach the dressing tubing to the pump tubing by pushing the Quick-connector together until you hear a click.

# Invia® Gauze Dressing with FitPad application guide



## Dressing Application Guide

Invia® Gauze Dressing Kit with FitPad



- 1. Thoroughly clean and debride the wound.**  
Apply skin prep to protect the peri-wound skin.



- 2. If required, apply a non-adherent contact layer** prior to placing the gauze into the wound.



- 3. Cut the gauze** to fit the size and shape of the wound. Do not cut the gauze directly over the wound.



- 4. Saturate the gauze with the saline** provided.



- 5. The gauze** should fit loosely into the wound bed. Do not tightly pack or force gauze into areas of the wound.



- 6. Apply transparent film.** Partially peel back one side of layer 1 – place the adhesive side down. Remove the remaining side of layer 1.



- 7. Now remove the transparent backing layer** labeled 2.



- 8. Remove the perforated silver colored tab** on the side. The film should extend 3–5 cm beyond the wound margin to facilitate an adequate seal.



- 9. Select appropriate location** for the suction pad (FitPad) to be applied. **Pinch the film and cut a small hole** (approx. 1 cm).



- 10. Peel the backing off the FitPad** to expose the adhesive.



- 11. Place the FitPad** centered over the previously cut hole in the dressing. Press firmly for adherence.



- 12. Attach the dressing tubing** to the pump tubing by pushing the Quick-connector together until you hear a click.



# Invia® Foam Dressings

## with Invia® Silverlon® NPWT application guide



### Dressing Application Guide

Antimicrobial Wound Contact Dressing

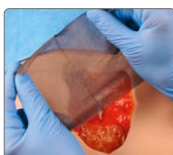
Application guide with the **Invia® Foam Dressing Kit with FitPad**



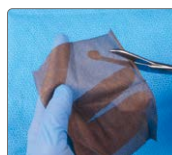
This Quick Card does not replace the instructions for use REF 200.9851 and 200.8923



**1. Cleanse wound** with normal saline, distilled water, or sterile water. Remove necrotic debris or eschar as needed.



**2. Select the appropriate size** of Invia Silverlon dressing that will fully cover the wound. (10 x 12 cm or 12 x 20 cm)



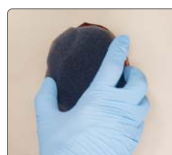
**3. Trim the dressing** as needed to ensure the dressing is in full contact with the wound bed, edges, or undermining.



**4. Activate the dressing** by thoroughly moistening with normal saline, distilled water or sterile water.



**5. Place the Invia Silverlon dressing** directly over the wound. Ensure dressing is in direct contact with the wound bed and edges. Either side can be used.



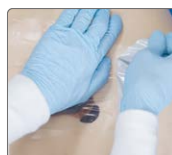
**6. Cut the foam** to the size and shape of the wound bed. **Place foam over contact dressing.** Do not pack tightly.



**7. Cover foam with transparent film.** Partially peel back one side of layer 1. Place the adhesive side down over the wound and remove the other part of layer 1.



**8. Now remove** the transparent backing film labeled 2.



**9. Remove the** perforated silver colored tab on the side. The film should extend 3-5 cm beyond the wound margin to facilitate adequate seal.



**10. Select** appropriate location for the external suction pad (FitPad) to be applied. Pinch the film and cut a **small hole** (approx. 1 cm).



**11. Peel off** the backing of the **FitPad** to expose the adhesive and **place over** the **previously cut hole** in the dressing. Press firmly for adherence.



**12. Attach** the dressing tubing to the pump tubing by pushing the **Quick-connector** together until you hear a click.

# Invia® Gauze Dressings with Invia® Silverlon® NPWT application guide



## Dressing Application Guide

Invia® Silverlon® NPWT Antimicrobial Wound Contact Dressing  
Application guide with the **Invia® Gauze Dressing Kit with FitPad**



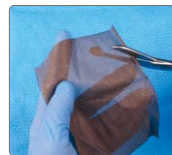
This Quick Card does not replace the instructions for use REF 200.9851 and 200.9065



**1. Cleanse wound** with normal saline, distilled water, or sterile water. Remove necrotic debris or eschar as needed.



**2. Select the appropriate size** of Invia Silverlon dressing that will fully cover the wound. (10 x 12 cm or 12 x 20 cm)



**3. Trim the dressing** as needed to ensure the dressing is in full contact with the wound bed, edges, or undermining.



**4. Activate the dressing** by thoroughly moistening with normal saline, distilled water or sterile water.



**5. Place the Invia Silverlon dressing** directly over the wound. Ensure dressing is in direct contact with the wound bed and edges. Either side can be used.



**6. Saturate gauze** with saline. **Place over the contact dressing.** The gauze should fill the wound cavity. Do not pack tightly.



**7. Cover gauze with film.** Partially peel back one side of layer 1. Place the adhesive side down over the wound and remove the other part of layer 1.



**8. Now remove** the transparent backing film labeled 2.



**9. Remove the** perforated silver colored tab on the side(s).



**10. Select appropriate location** for the external suction interface FitPad. **Cut a small hole** in the transparent film, no more than 1 cm in diameter.



**11. Peel off the** backing of the **FitPad** to expose the adhesive and **place over the previously cut hole** in the dressing. Press firmly for adherence.



**12. Attach the** dressing tubing to the pump tubing by pushing the **Quick-connector** together until you hear a click.

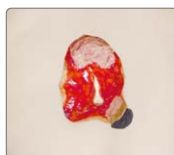
# Dressing application guide bridging the Invia® FitPad



## Dressing Application Guide

Invia® Foam Dressing Kit with FitPad: **Bridging the FitPad**

Two wounds of similar etiology may be bridged utilizing one dressing kit



**1. Thoroughly clean and debride the wound.**  
Apply skin prep to protect the peri-wound skin.



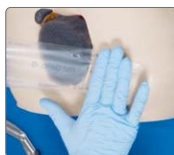
**2. Cut the foam** to fit the size and shape of the wound. Do not cut directly over the wound. Rub the edges of the foam to remove any loose particles.



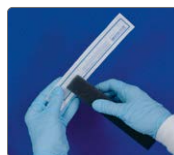
**3. Place the foam** into the wound cavity. Do not tightly pack or force foam into areas of the wound. Do not allow the foam to overlap onto intact skin.



**4. Select an area** to relocate the FitPad (non-weight bearing area). **Apply transparent film** over any intact skin between the wound and the relocation site.



**5. Partially peel** back one side of layer 1, and place the adhesive side down. Now remove the transparent backing labeled 2. Finally remove the perforated silver colored tab on the side.



**6. Cut a foam "bridge", 3 cm wide**, that will be long enough to connect the wound with the relocation site (maximum **40 cm long**). Ensure the "bridge" is large enough to accommodate the FitPad at the relocation site.



**7. Apply the "bridge"** on the transparent film between wound and relocation site. Ensure it has good contact with the foam in the wound and has no contact with unprotected skin.



**8. Apply transparent film to cover all of the foam:** wound and the "bridge" foam. Follow the film application instructions described under step 5.



**9. Multiple pieces** of film can be used. The film should extend 3-5 cm beyond the margin of the foam dressing to facilitate an adequate seal.



**10. Select a central area** to place the FitPad on the relocation site. Pinch the film lifting slightly and cut a small hole (approx. 1 cm).



**11. Peel off the** backing of the FitPad to expose the adhesive. **Place the FitPad** centered over the previously cut hole. Press firmly for adherence.



**12. Attach the** dressing tubing to the pump tubing by pushing the **Quick-connector** together until you hear a click.

# Dressing application guide bridging two wounds



## Dressing Application Guide

Invia® Foam Dressing Kit with FitPad: **Bridging two wounds**



**1. Thoroughly clean and debride the wounds.**  
Apply skin prep to protect the peri-wound skin.



**2. Cut the foam** to fit the size and shape of the two wounds. Do not cut directly over the two wounds. Rub the edges of the foam to remove any loose particles.



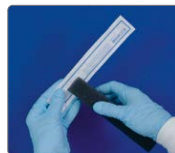
**3. Place the foam** in each wound cavity. Do not tightly pack or force foam into areas of the wounds. Do not allow foam to overlap onto intact skin.



**4. Apply transparent film** over any intact skin **between the two wounds**: this is where your "bridge" will be placed.



**5. Partially peel back** one side of layer 1, and place the adhesive side down. Now remove the transparent backing labeled 2. Finally remove the perforated silver colored tab on the side.



**6. Cut a foam "bridge", 3 cm wide**, that will be long enough to connect the two wounds and touch the foam in both wounds (maximum 40 cm long).



**7. Connect the two wounds** by placing the foam "bridge" on the transparent film between the wounds. Ensure it has good contact with the foam in the wounds and has no contact with unprotected skin.



**8. Apply transparent film to cover all of the foam**: wound and the "bridge" foam. Follow the film application instructions described under step 5.



**9. Multiple pieces** of film can be used. The film should extend 3–5 cm beyond the margin of the foam dressing to facilitate an adequate seal.



**10. Select a central area** over one of the wounds to place the FitPad (non-weight bearing area). Pinch the film lifting slightly and cut a **small hole** (approx. 1 cm).



**11. Peel off the backing** of the FitPad to expose the adhesive. **Place the FitPad** centered over the previously cut hole. Press firmly for adherence.



**12. Attach the dressing tubing** to the pump tubing by pushing the **Quick-connector** together until you hear a click.

- Application guide for foam and closed surgical incisions
- Application guide for gauze and closed surgical incisions

# Dressing Application Guide

## Closed surgical incisions



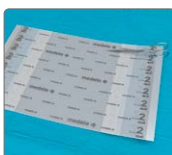
## Closed surgical incisions

### Dressing Application Guide

Invia® Foam Dressing Kit with FitPad



1. Clean and dry application site per physician's order. Apply skin prep to protect the peri-incisional skin.



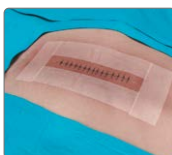
2. Cut a few strips (3 cm wide) from Transparent Film to protect the peri-incisional skin. Retain a portion of the handling bars on each piece.



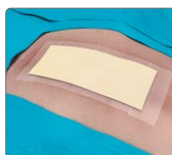
3. Apply strips. Partially peel back layer 1 and place the adhesive side down along the suture or staple line. Leave the suture line exposed.



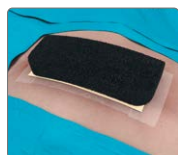
4. Remove side layer 1 and top layer 2 and detach silver colored handling bar.



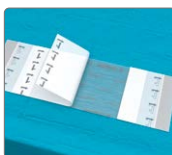
5. "Picture frame" the suture or staple line with Transparent Film as shown in the picture to protect the peri-incisional skin.



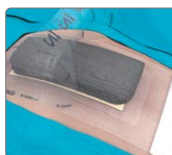
6. Protect the entire incision line with a non adherent contact layer. Extend this by at least 2.5 cm at either end of the incision.



7. Cut the foam into minimum 5 cm wide strips. Place over contact layer to cover at least 2.5 cm over either end of the incision.



8. Cut the Transparent Film to allow for coverage 3-5 cm beyond the foam strips. Remove central layer 1 of the film.



9. Apply transparent film over the full surface of foam, extending around intact skin and remove further layer as described in step 4.



10. Select appropriate location for the FitPad. Pinch film and cut small hole (approx. 1 cm).



11. Peel off the backing of the FitPad and center the FitPad over the previously cut hole. Press firmly for adherence.



12. Connect the dressing tubing to the pump tubing by pushing the Quick-connector together until you hear a click.

# Dressing Application Guide

## Closed surgical incisions



## Closed surgical incisions

### Dressing Application Guide

Invia® Gauze Dressing Kit with FitPad



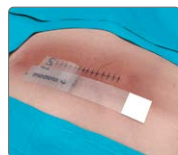
1. Clean and dry application site per physician's order. Apply skin prep to protect the peri-incisional skin.



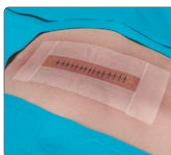
2. Cut a few strips (3 cm wide) from Transparent Film to protect the peri-incisional skin. Retain a portion of the handling bars on each piece.



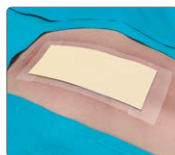
3. Apply strips. Partially peel back layer "1" and place the adhesive side down along the suture or staple line. Leave the suture line exposed.



4. Remove side layer "1" and top layer "2" and detach silver colored handling bar.



5. "Picture frame" the suture or staple line with Transparent Film as shown in the picture to protect the peri-incisional skin.



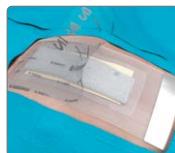
6. Protect the entire incision line with a non adherent contact layer. Extend this by at least 2.5 cm at either end of the incision.



7. Cut or fold the gauze into minimum 5 cm wide strips. Place over contact layer to cover at least 2.5 cm over either end of the incision.



8. Cut the Transparent Film to allow for coverage 3–5 cm beyond the gauze strips. Remove central layer "1" of the film.



9. Apply transparent film over the full surface of gauze, extending around intact skin and remove further layer as described in step 4.



10. Select appropriate location for the FitPad. Pinch film and cut small hole (approx. 1 cm).



11. Peel off the backing of the FitPad and center the FitPad over the previously cut hole. Press firmly for adherence.



12. Connect the dressing tubing to the pump tubing by pushing the Quick-connector together until you hear a click.

## Tunneling application

**The Invia® NPWT System should not be used to treat unexplored tunnels or sinus tracts.**

Measure the length of the tunnel to be treated and document in the patient's notes. Ensure that any nonviable tissue (eschar or slough) has been debrided from the tunnel area and has been cleansed per facility protocol. Cover any areas of the tunnel that need protection ( i.e., bone, tendon ) with a wound contact layer. Select a wound filler (Invia charcoal coloured foam or Invia White foam) based on the tunnel assessment. Cut a section of the foam to the measurement of the tunnel plus an additional 1 – 3 cm. Wrap the charcoal coloured foam intended for the tunnel with a non-adherent contact layer to prevent breakage or fraying. If using the Invia White foam, this is non adherent and does not require a non adherent contact layer. The wound filler should be gently placed all the way into the tunnel and then withdrawn by 1 – 2 cm.

Ensure the dressing selected can be easily removed from the wound without the risk of dressing retention. Ensure that the tunnel is not overpacked as this can result in impaired wound healing and tissue damage. Continue to dress the remaining area of the wound, ensuring that the tunnel piece of foam extending from the tunnel touches the wound filler in the rest of wound. Cover the wound area with transparent film. Cut a hole in the film, 1cm by 1cm. Peel off the backing of the FitPad to expose the adhesive and place over the previously cut hole in the dressing. Press firmly for adherence. Attach the dressing tubing to the pump tubing by pushing the Quick-connect together until you hear a click. Document the number and types of wound dressings ( including wound contact layer ) placed in the wound to ensure all are retrieved at the next dressing change.

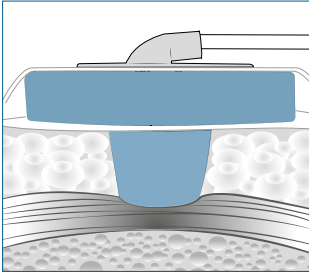
## Undermining application

Measure the length of the undermining area to be treated and document in the patient's notes. Ensure that any nonviable tissue (eschar or slough) has been debrided from the undermining area and has been cleansed per facility protocol. Cover any areas that need protection ( i.e., bone, tendon ) with a wound contact layer. Select a wound filler (Invia charcoal coloured foam or Invia White foam) based on the assessment of the undermining. Cut a section of the foam to the measurement of the undermining area plus an additional 1 – 3 cm. Wrap the charcoal coloured foam intended for the undermining area with a non-adherent contact layer. If using the Invia White foam, this is non adherent and does not require a non adherent contact layer. The wound filler should be gently placed into the undermining area and withdrawn slightly.

Ensure the dressing selected can be easily removed from the wound without the risk of dressing retention. Ensure that the undermining area is not over-packed as this can result in impaired wound healing and tissue damage. Continue to dress the remaining area of the wound, ensuring that the undermining area piece of foam extends and touches the wound filler in the rest of wound. Cover the wound area with transparent film. Cut a hole in the film, 1cm by 1cm. Peel off the backing of the FitPad to expose the adhesive and place over the previously cut hole in the dressing. Press firmly for adherence. Attach the dressing tubing to the pump tubing by pushing the Quick-connector together until you hear a click. Document the number and types of wound dressings ( including wound contact layer ) placed in the wound to ensure all are retrieved at the next dressing change.



## Dressing wounds smaller than the Invia® FitPad



If the wound is smaller than the surface area of the Invia FitPad the following dressing technique may be used to protect the periwound skin.

Prepare the periwound skin with a skin protective barrier wipe. Cover the periwound skin approximately 6–8 cm beyond the wound edge with transparent film.

**Prepare either the foam or gauze wound filler as follows:**

### **Foam**

- Cut the foam into an appropriate size corresponding with the dimensions of the small wound cavity. Do not cut the foam over the wound.
- Rub the foam edges to remove any loose particles. Cover any areas of wound that need protection (i.e., bone, tendon) with a wound contact layer. Gently place the foam in the wound cavity, covering the entire wound base and sides, tunneling and undermining. Dressing should fit loosely in the wound. Do not force or pack.
- Cut another piece of foam to accommodate the size of the Invia FitPad plus an additional 1–2 cm.
- Place this foam on the wound surface making sure the foam communicates with the foam in the wound. **This foam should be on top of the transparent film that is protecting the periwound skin.**
- Cover this area with film.
- Peel back one side of layer 1 and place adhesive side down, do not stretch or pull the film.
- Remove the remaining part of layer 1.
- Remove the backing film labeled 2.
- Remove the perforated silver colored handling bar on the side.
- Cut a hole 1cm x 1cm into the film.
- Apply the Invia FitPad over the hole.
- Gently press this down.
- Connect the Invia FitPad tubing to the canister tubing.
- Commence NPWT.
- Ensure that the foam collapses.

## Gauze

- Cut the gauze into an appropriate size corresponding with the dimensions of the small wound cavity. Cover any areas of wound that need protection (i.e., bone, tendon) with a wound contact layer.
- Saturate the antimicrobial gauze with saline. Squeeze excess saline leaving the gauze moist. Open and fluff the gauze into the wound completely filling the wound to the level of the skin. Do not excessively pack the wound as this may cause further tissue damage and increase the wound size.
- Cut and shape another piece of gauze to accommodate the size of the Invia FitPad plus an additional 1 – 2 cm.
- Place this gauze on the wound surface making sure the gauze communicates with the gauze in the wound. **This gauze should be on top of the transparent film that is protecting the skin.**
- Cut the film to the appropriate size and shape, allowing an overlap of 3–5 cm onto surrounding skin.
- Apply the transparent film dressing over the entire wound, extra filler for the Invia FitPad and surrounding skin.
- Press and smooth the transparent film dressing down firmly around the entire wound area.
- Cut a hole over the dressed wound by pinching and lifting slightly on the transparent film.
- Center and apply the Invia FitPad directly over the hole in the film.
- Connect the Invia FitPad tubing to the canister tubing.
- Commence NPWT.
- Ensure that the gauze collapses.

# SPECIAL CONSIDERATIONS

## Care setting 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.

If during transfer the therapy is discontinued for more than 2 hours, the dressing should be replaced and therapy restarted.

## Use with Hyperbaric Oxygen Chamber (HBOC)

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 Invia 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 Invia Fitpad connector with an appropriate sterile dressing. After HBO therapy has been completed, the dressing may be reconnected and therapy with the Invia NPWT System restarted. It is advisable to use an alcohol wipe or replace the tubing before reconnecting the Invia 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 Invia NPWT System dressing may be visible on some radiological images.

### X-ray

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

- The Invia NPWT pump can be taken into the X-ray room and its position adjusted by the technician to allow 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.

### Computerized Tomography (CT)

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

- The Invia NPWT pump can be taken into the scan room and its position adjusted by the technician to allow 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 Invia 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 Invia NPWT 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.
- Consider removing the entire dressing and tubing prior to MRI scanning. The wound can be covered with an alternative dressing during the procedure and NPWT re initiated afterwards.

## Defibrillation

The Invia NPWT pump should be disconnected prior to defibrillation directly over the site.

- Consider removing the dressing if any components may compromise the delivery of the defibrillation.

## Allergic reaction

All components and packaging of the Invia 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 or physician immediately. Retain the batch number of dressing and contact Medela regarding the allergic reaction.

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