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# Pre-clinical Evidence
# Invia® Abdominal Dressing Kit

## Negative Pressure Wound Therapy (NPWT) for open abdomen management

Precious life,
progressive care

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# Context

**Medela's Invia Abdominal Dressing Kit provides an effective solution for the management of open abdomen (OA) with exposed viscera and organs.**

This document will:

- Provide a brief introduction to the use of NPWT in the management of open abdomen (OA)
- Describe the Invia Abdominal Dressing Kit
- Present pre-clinical evidence of the Invia Abdominal Dressing Kit in conjunction with the Invia Liberty NPWT System supporting its use as an effective solution for the management of OA.

# Introduction

## Indications and Clinical Rationale of the Open Abdomen (OA) Management

Open abdomen is an abdominal wall defect created by intentionally leaving an abdominal incision open at the completion of intra-abdominal surgery or by opening (or reopening) the abdomen because of concern for abdominal compartment syndrome. OA can also be the result of damage control laparotomy, or scenarios where closure of an abdominal defect is not possible or desired.[1] This approach has been adopted in many indications including trauma (e.g. intra-abdominal haemorrhage),[2] septic or contaminated abdomen (e.g. peritonitis)[1] and some emergency vascular indications (e.g. ascending aortic aneurisms)[3]. Another important use of OA therapy is in the management or prevention of abdominal compartment syndrome (ACS).[1]

## Historical Perspective

OA therapy has long been recognized to reduce mortality in patients with abdominal sepsis.[1] For many decades, suboptimal techniques to manage the OA, led to a high incidence of major complications and OA therapy was considered as a last resort.[4] Clinicians developed temporary abdominal closure (TAC) methods, focussing on "home-made" solutions, often with local variations.[4,5] Examples included the Bogota bag technique (in which a 3-litre sterile irrigation bag is sutured to the fascial edges to contain and protect the abdominal contents)[4] and the vac-pack technique (in which sterile surgical towels are placed within the abdominal wound, covered with an airtight drape and attached to wall suction via a drain).[4] These early TAC methods improved the complication rates to more acceptable levels. This permitted adoption of OA as a first line therapy for patients with abdominal trauma and eventually this expanded to include other indications such as damage control surgery (DCS) for non-trauma patients.[1,2,4] More recently, further progress has been made through the development of commercial NPWT-based Abdominal Dressings. This has allowed the application of a TAC method[4] that is more reliable and convenient, and the use of NPWT to manage the OA is becoming the method of choice.[4,5]

## Key Features of a good Temporary Abdominal Closure Device

### Protects exposed organs

Protecting the exposed organs and preventing visceral adherence to the abdominal wall is one of the most important requirements of a TAC technique.[4] Through the use of a visceral protective drape and constant negative wound pressure, the NPWT abdominal technique prevents visceral adherence to the anterolateral abdominal wall while maintaining medial fascial traction.[7]

### Removes abdominal fluid

Large quantities of fluid can be generated during the OA management, therefore any TAC method will need to have excellent fluid handling capabilities.[4] One major advantage of NPWT over the other TAC techniques is its ability to actively drain fluid as a result of the application of negative pressure reducing the pooling of sterile or contaminated fluid within the abdominal cavity.[11]

### Safe and easy application and removal

Patients with OA often require multiple re-operations. A desirable feature of a TAC method is ease of application and removal. Suture-less application techniques such as NPWT are easier to apply and remove than those which involve suturing.

### Minimises loss of abdominal domain

It is advisable to close an OA as soon as considered safe to do so.[6] Without application of an active system, such as NPWT, the edges of the laparotomy incision might retract over time, leading to large ventral abdominal wall hernias. This causes major morbidity as well as requiring major reconstructive surgery to correct, many months later. TAC methods that can help to maintain abdominal domain, by stabilising the edges of the wound close to the midline, are therefore advantageous. The use of NPWT maintains a medial fascial traction which may enhance fascial closure rate.[7]

### Facilitates primary fascial closure

TAC methods which minimise fascial retraction, such as NPWT will facilitate primary fascial closure[8,9] and consequently, reduce complication rates.[6] Several systematic reviews have reported improved rates of primary fascial closure when NPWT is used, compared with alternative methods of TAC, such as Bogota Bag.[8,10] Addition of sequential dynamic closure techniques, such as dynamic retention sutures, to NPWT can further increase the rate of fascial closure.[8]

### Minimises complications

In patients with OA, their abdominal contents are exposed and need to be protected. Unprotected bowel is prone to desiccation, iatrogenic trauma, and fistula formation[8]. Maintaining the abdomen in a moist environment as a result of the NPWT top layer adhesive film also prevents uncontrolled evaporative fluid loss, secondary external bacterial contamination and reduces heat loss[11]. The use of the organ contact layer is essential to protect the abdominal contents from contact with the polyurethane foam and to reduce the risk of fistula formation.

### Facilitates nursing care and patient transport

Efficient containment of large volumes of fluid is an advantage of NPWT systems and greatly facilitates the nursing care of patients undergoing OA therapy.[8] Commercial NPWT systems with portable pumps, allow patients to be transport with no interruption in therapy.

Commercial NPWT Abdominal Systems perform well against all required features of a good TAC device (Figure 1).[4 5,11], and international consensus guidelines recommend that NPWT be used, rather than not used, to manage the OA.[12,13]

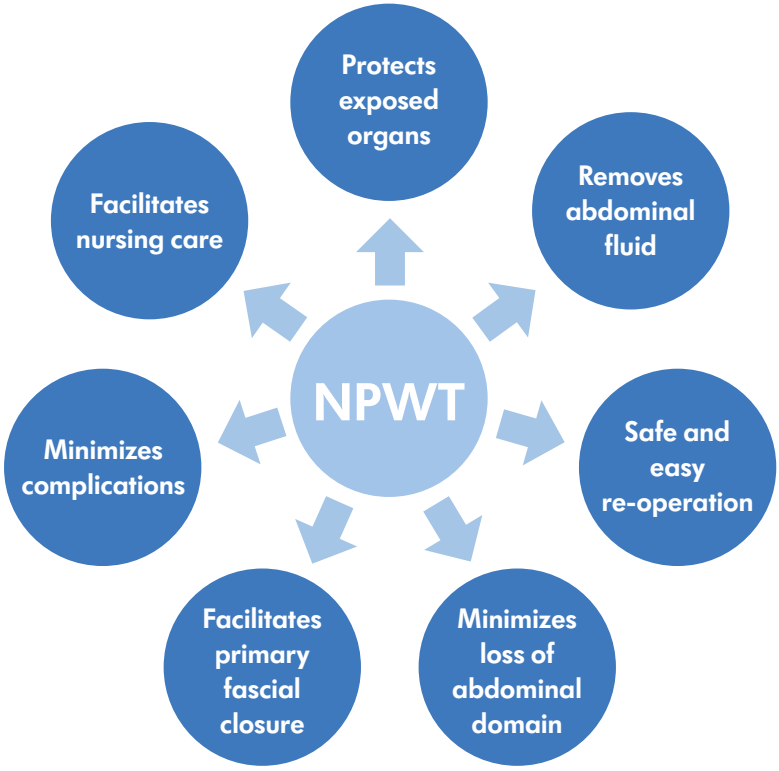



**Figure 1 –** NPWT Abdominal Systems perform well against all required features of a good TAC device. Modified from [4,5,11]

## Key messages

- International consensus guidelines agree and recommend NPWT to be used, rather than not used, among critically ill or injured patients with open abdominal wounds. [12,13]
- Commercial NPWT abdominal systems, are all composed of similar basic components – a fenestrated sheet to protect the abdominal organs (organ contact layer), polyurethane foam, airtight drape and a NPWT pump for delivery of consistent and reliable negative pressure and efficient fluid removal. [11,13]

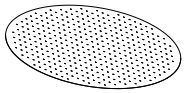
# Invia Abdominal Dressing Kit

## Description

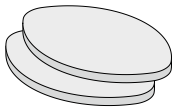
Medela's Invia Abdominal Dressing Kit in conjunction with the Invia Liberty NPWT system (Figure 2) is indicated for the management of open abdominal wounds with exposed viscera and organs, including abdominal compartment syndrome. It consists of an organ contact layer, two pre-cut foam pads, four transparent films and a suction interface (Invia FitPad). Features of the Invia Liberty system of particular benefit in the high fluid environment of the OA, are the 5 l/min pump flow capacity, the 800 ml canister and the "high leakage" setting. This setting allows more time (5 min) for "draw down" (removal of air from the system and abdomen and establishing the set pressure) thus reducing the chance of false leakage alarms occurring.

Moreover, the Invia NPWT System with FitPad features Intelligent Pressure Control with Dynamic Exudate Removal to help ensure NPWT is reliably delivered and controlled at the wound site.

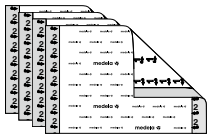
**Invia Abdominal Dressing Kit**



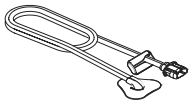
Easy to apply, organ contact layer (OCL); oval polyurethane film with fenestrations protects the abdominal contents and enables fluid drainage from the abdomen.



Simplified pre-cut foam design; oval polyurethane foam distributes negative pressure across the wound surface and allows passage of fluids and exudates.



Transparent Film; thin transparent polyurethane film with acrylic adhesive fixates the wound filler and provides an airtight seal; intuitive handling.



Invia FitPad with dual lumen tubing; distributes negative pressure to the wound; provides dynamic exudate removal and intelligent pressure control.

**Invia Liberty**

Invia Liberty NPWT System; provides reliable exudate management and pressure control from the pump to the wound.

**Figure 2 –** Components of the Invia Abdominal Dressing Kit to be used with the Invia Liberty NPWT pump

## Indications

The Invia Abdominal Dressing Kit is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries may be required. Its intended use is with patients who have open abdominal wounds with exposed viscera and organs, and including but not limited to patients with abdominal compartment syndrome.
It is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre. The Dressing Kit is intended to be used together with the Invia Liberty NPWT System.

## Contraindications

- Direct positioning of NPWT foam over exposed organs, large veins and arteries, anastomotic sites, tendons or nerves (unless suitably covered with the Organ Contact Layer)
- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Malignancy in wound

Note: Specific indications, contraindications, warnings, precautions, and safety information exist for the Invia Abdominal Dressing Kit and Invia Liberty NPWT System products. Please consult the respective Instructions for Use prior to application.

# Pre-clinical evidence

**Pre-clinical tests were carried out to demonstrate the performance of the Invia Abdominal Dressing in conjunction with the Invia Liberty NPWT System with a particular focus on the efficient pressure distribution and fluid management as well as the safety and ease of application and removal. Results have yet to be verified in human trials.**

## In vitro performance testing of the Invia Abdominal Dressing

The key to intra-peritoneal fluid removal has been the application of negative pressure in order to vacuum out the fluid. The efficiency of negative pressure delivery is therefore paramount in the successful delivery of therapy when managing the OA. [14]

### Methods

An in vitro abdominal model (Figure 3), similar to a model previously described in the literature [15], was used to investigate the pressure distribution and fluid handling capability of the Invia Abdominal Dressing in conjunction with Invia Liberty NPWT System.

- Pressure sensors were applied in 4 concentric zones, in order to measure the pressure distribution beneath the dressing (organ contact layer) from a central location (where the Invia FitPad was positioned) to the most lateral location (representing the paracolic gutters of the OA).
- To simulate the uneven bowel surface contours, silicone tubings were overlaid inside the wound model.
- The model was preloaded with 1000 ml of an artificial wound fluid to simulate the fluid accumulated in the abdominal cavity prior to the application of the NPWT.
- Continuous negative pressure was applied using the Invia Liberty pump, set at –125 mmHg.
- The ability of the Invia Abdominal Dressing in conjunction with the Invia Liberty NPWT System to manage the pre-loaded fluid was assessed in the first 30 minutes of therapy.
- Over a subsequent 73-hour period, the fluid handling capability of the System was assessed by instilling 700 ml/24 h of artificial wound fluid into the model.

**Figure 3 –** Top view of the in vitro abdominal model

## Pressure Distribution Results

Negative pressure was evenly distributed in zones A, B, C and D. Delivered pressure in the centre of the dressing (zone D; see figure 4), beneath the centrally applied foam and beneath the organ contact layer measured throughout the course of the study, was –123 mmHg. The most distally measured pressure, (zone A; see figure 4) was –119 mmHg over 73 hours. These values showed a stable vacuum performance within 10 % of the target pressure of –125 mmHg, underneath the entire dressing.

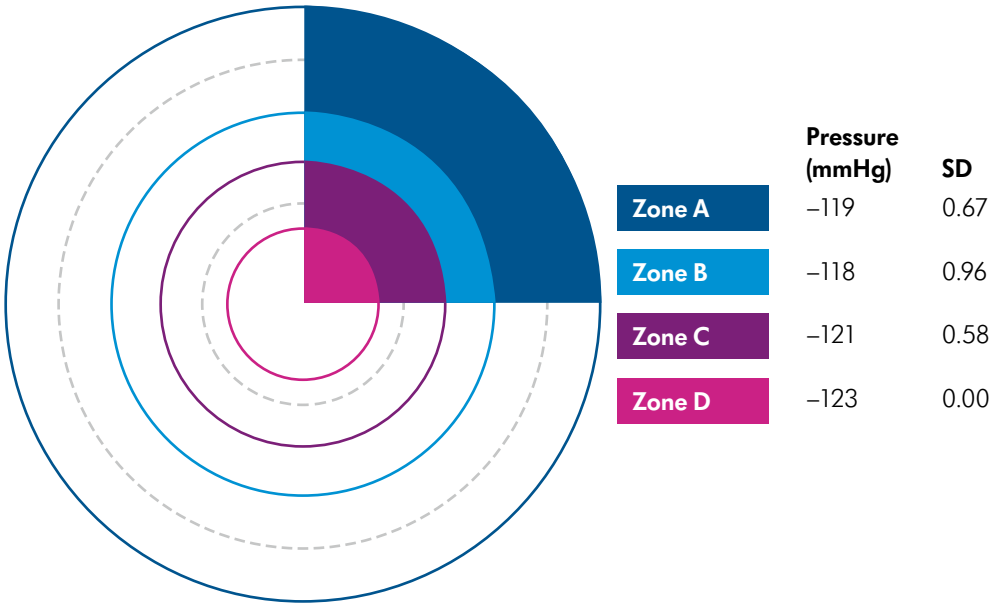



**Figure 4 –** Pressure distribution in an abdominal wound benchtop model with the Invia Abdominal Dressing Kit used in conjunction with the Invia Liberty NPWT System. Values shown are mean mmHg (SD). Pressure values were recorded along with mean values at initial onset of NPWT and throughout a 73 hour application time. N=3

## Key messages

- Negative pressure was effectively delivered and was evenly distributed throughout the entire area of the Invia Abdominal Dressing.
- Slight reduction in negative pressure was observed in the periphery of the Invia Abdominal Dressing (Zone A) compared with the pressure transmitted immediately beneath the Invia FitPad (Zone D, values adjusted respecting hydrostatic force within the sensor pathway inside the model).

## Fluid Management Results

Over the first 30-minute period, nearly 75% (746 ml +/–22 ml) of the initially applied fluid (1000 ml) was removed into the canister. The test results confirm efficient fluid evacuation from the wound model correlating to the results published in the referenced data, where the value of the best performing abdominal kit was 802 ±20 ml (during the 30 minutes test when 1000 ml fluid was pre-filled into the wound model).[15]

The residual amount of fluid contained in the open space structure of the reticulated polyurethane foam was determined to be approximately 110 ml.

The remaining residual fluid was contained in the open space between the silicon tubings of the model. This also supports the measurements recorded over 73 hours.

Fluid removal was measured over the subsequent 73 hours using a simulated exudate fluid rate of 700 ml/24 hr. Fluid removal was observed to progress steadily and the rate of fluid removal into the canister reflected the rate of fluid instilled into the model. In total, 93 % (2712/2902 ml) of all the instilled fluid was removed into the canisters (Figure 5) indicating effective fluid management.

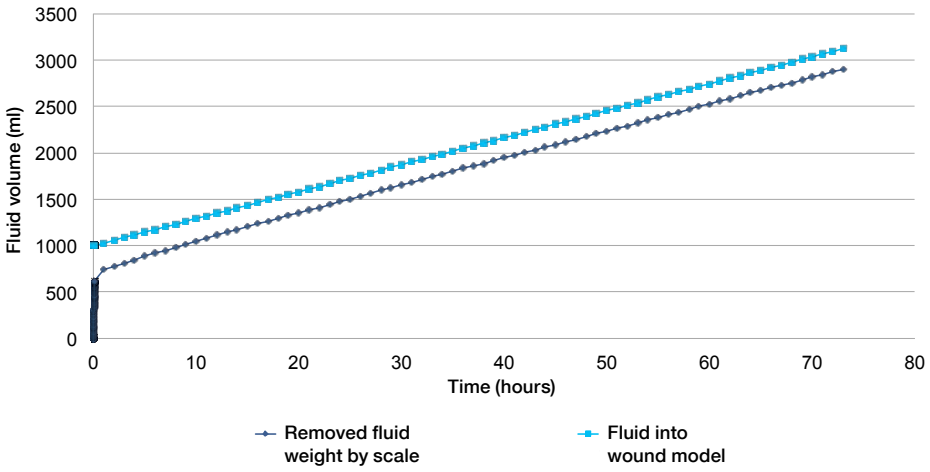



**Figure 5 –** Total fluid handling over 73 hours in vitro. Mean (SD), n=3

## Key messages

- Invia Abdominal Dressing in conjunction with Invia Liberty NPWT System effectively managed the instilled fluid by removing 93 % into the canisters.
- This is comparable with other commercial negative pressure abdominal dressing systems assessed using a similar benchtop model.[15]

## In vivo analysis of the Invia Abdominal Dressing System

Although patients treated with abdominal NPWT typically receive negative pressures of –125 mmHg, for some patients a lower negative pressure setting may be more appropriate (for example where ischaemic bowel is present or suspected). The impact of lower negative pressure settings on clinical and functional outcomes in managing the OA, is currently poorly understood. A porcine model of the OA was used to investigate **fluid handling profile and wound contraction** by using the Invia Abdominal Dressing in conjunction with Invia Liberty NPWT system at two set negative pressures (–125 and –75 mmHg).

### Methods

- A 30 cm laparotomy incision created an open abdomen in a pig model (n=6). A tube was inserted into the pouch of Douglas to pre-fill the abdominal cavity with 500 ml of fluid.
- Invia Abdominal Dressing was applied and NPWT initiated at either –125 mmHg (n=3) or –75 mmHg (n=3).
- After 30 minutes, additional fluid was instilled at a rate of 6 litres/24 hours. Fluid handling was monitored for 48 hours in total.
- The dimensions of the laparotomy incision were recorded before application of the NPWT, as well as during and after 48 hours of treatment with Invia Abdominal Dressing Kit and Invia Liberty NPWT system, at both –125 mmHg and –75 mmHg pressure settings.

### Fluid Handling Results

While benchtop studies demonstrated excellent fluid handling capability of the Invia Abdominal Dressing in conjunction with the Invia Liberty NPWT system, the ability to manage large volumes of fluid was evaluated further in an animal model of the OA, using fluid volumes designed to challenge the system and represent a "worst-case" clinical scenario.

Over the first 30 minutes of fluid removal, a fast, initial removal of the pre-filled fluid was observed with the majority of the fluid being removed in the first 10 minutes of therapy. This initial rapid evacuation of fluid was followed by a plateau phase (Figure 6). This initial fluid handling profile of the Invia Abdominal Dressing is consistent with studies investigating other commercial NPWT devices designed for use in the OA.[14–16]
The removal of fluid into the canister in the first 10 minutes of therapy was marginally faster when NPWT was set at –125 mmHg, compared with –75 mmHg, although no difference between the two pressure settings was apparent by 30 minutes (Figure 6). After 30 minutes of NPWT, a mean volume of 376 (75 %) and 386 ml (77 %) of the initial 500 ml volume, respectively, was removed into the canister. The proportion of fluid removed during the initial 10 minute[7,14] period was similar to other studies investigating other NPWT systems.

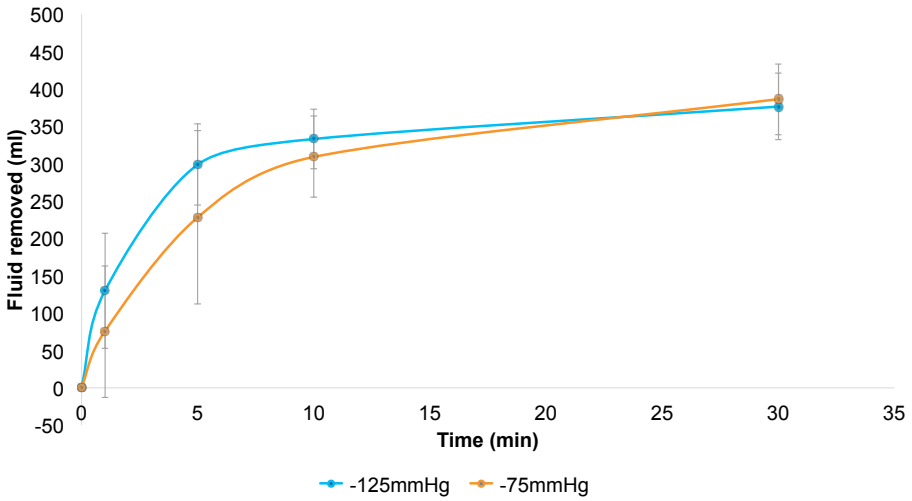



**Figure 6 –** Fluid handling over 30 minutes at two different NPWT pressure settings. Mean (SD), n=3.

Over a period of 48 hours, a total of 11.5 litres of fluid was instilled into the model. In the open abdomen managed with –125 mmHg, 86 % of the instilled fluid was removed over this period. When the open abdomen was managed with –75 mmHg, 81% of the fluid was removed (Figure 7).

Similar to the in vitro model, approximately 110 ml of fluid was retained into the open structure of the reticulate foam.

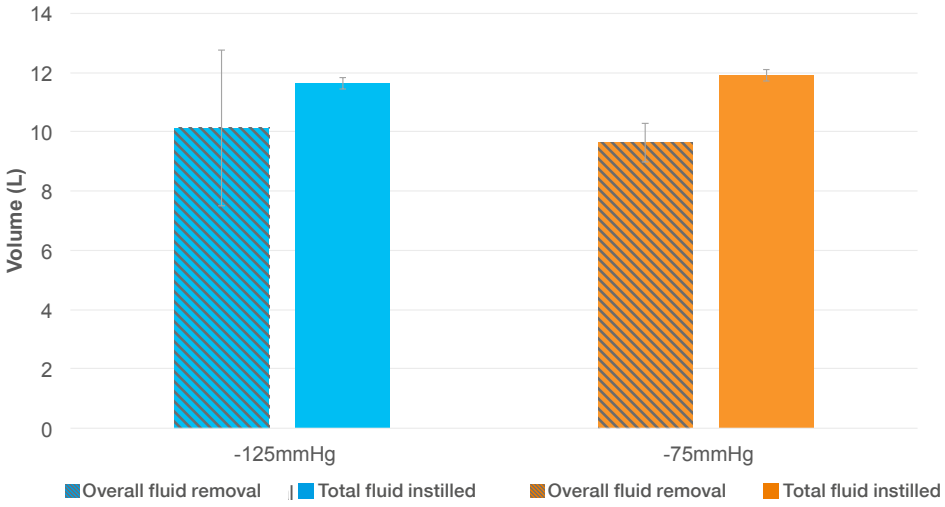



**Figure 7 –** Fluid handling following infusion of fluid over 48 hours. Mean (SD), n=3.

## Key messages

- The Invia Abdominal Dressing demonstrated efficient fluid handling capability in vivo under conditions of high fluid volume (approx. 6 l/day).
- Fluid handling was comparable between two different and clinically appropriate negative pressure settings, –75 mmHg and –125 mmHg.
- NPWT efficiently removed fluid in OA models even at the lower pressure setting of –75 mmHg.

## Wound Contraction Results

A key requirement of a good TAC method is to facilitate eventual fascial closure. To achieve this aim, it is important to minimise the loss of abdominal domain by maintaining the incisional edge as close as possible to the mid-line, preventing the lateral retraction of the fascia and the abdominal wall. The porcine OA model was used to investigate the effect of NPWT on the dimensions of OA incisions and whether any retraction of the wound edges was observed over 48 hours of treatment with the Invia Abdominal Dressing.

Uniform laparotomy incisions 30 cm in length were created along the midline. Before the Invia Abdominal Dressing was applied, natural "gap" of the abdominal wall resulted in an incisional width ranging from 13.1 to 14.2 cm at the widest point. Ideal TAC methods should minimise the width of the wound and maintain the wound edges as close to the midline throughout the duration of therapy and should minimise retraction of the abdominal wall. Following the application of the Invia Abdominal Dressing and initiation of therapy at –125 mmHg, the width of abdominal incision had reduced to 8.1 cm, a mean reduction in width of 40.3 %. Application of the Invia Abdominal Dressing at –75 mmHg had a similar effect with the mean width of the incision reducing to 8.7 cm, a reduction of 35.9 % (Figure 8). Similar reductions in width, (to approximately 8 cm) have been reported with other commercial abdominal dressings used in a similar experimental model.[7]

Continuous negative pressure was applied throughout the subsequent 48 hours. Wound contraction was maintained for 48 hours; the incisional wound edges were stable, with no signs of lateralization in any group during the experimental period.

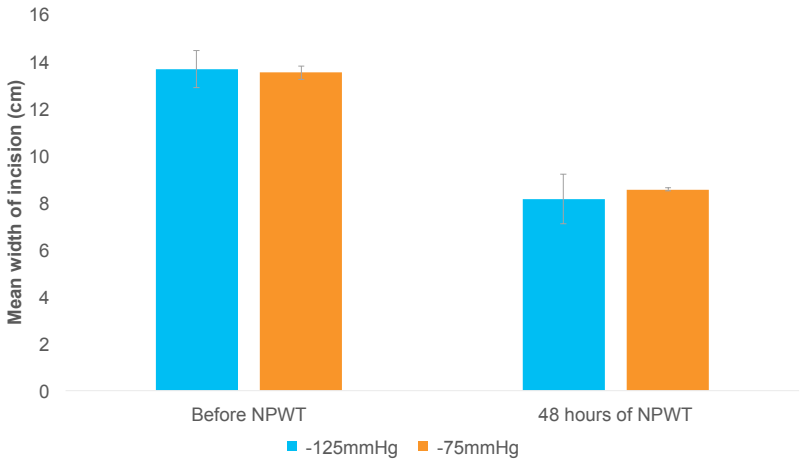



**Figure 8 –** Changes in the width of the abdominal incision before and after min 48 hours treatment with Invia Abdominal Dressing at –125 mmHg and –75 mmHg. Mean (SD); n=3.

## Key messages

- The Invia Abdominal Dressing can reduce the width of the abdominal incision.
- It is important to maintain abdominal domain to facilitate eventual fascial closure.

# Conclusions

In a series of pre-clinical analyses, the Invia Abdominal Dressing performed well against several key features needed to provide effective TAC:

- In an in vitro test, negative pressure was distributed equally underneath the entire surface of the organ contact layer
- High levels of fluid were consistently well managed by the Invia Abdominal Dressing both in vitro and in vivo
- Application of NPWT was observed to stabilise the laparotomy incisions in vivo. No abdominal wall retraction was observed over 48 hours of application

The Invia Abdominal Dressing is an appropriate TAC method for the management of the OA.

"We performed an animal study on 6 pigs to evaluate the Medela Abdominal Dressing performance in conjunction with the Liberty NPWT system set at different pressure levels. Based on our previous research studies and experience, I must say that **we were impressed about the ease of dressing application and excellent system performance**", stated assoc. Professor Sandra Lindstedt and Professor Richard Ingemansson from the University of Lund, Sweden.

# Abbreviations

- ACS, abdominal compartment syndrome
- NPWT, negative pressure wound therapy
- OA, open abdomen
- SD, standard deviation
- TAC, temporary abdominal closure

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