Invia® NPWT System

Clinical Evidence

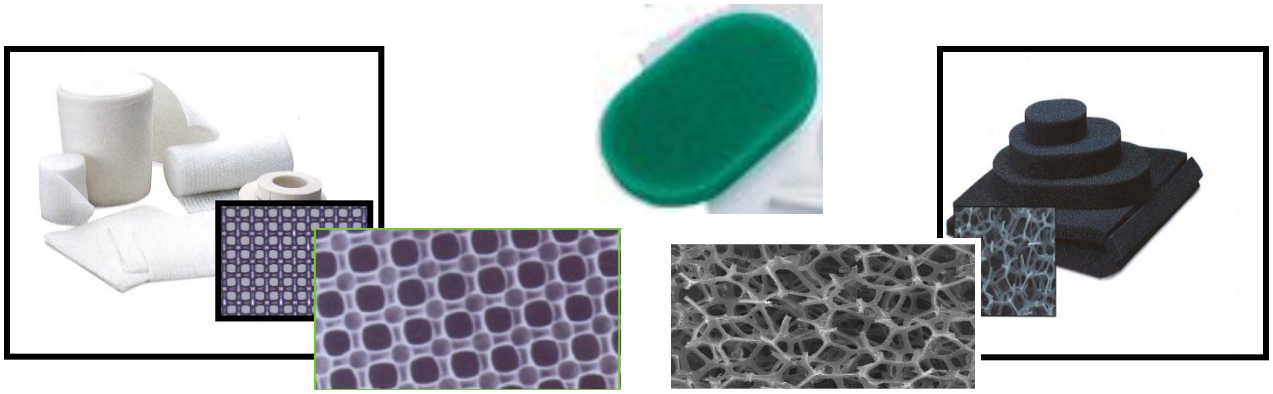
Invia® Negative Pressure Wound Therapy Clinical Evidence

AHRQ NPWT Technology Assessment 2009

Medicare Improvements for Patients and Providers Act of 2008 required the Secretary to evaluate existing HCPCS codes

Conclusion

- Current **evidence *does not* support** that one type of **dressing is superior to any other**
- **No NPWT system** has been **proven** to be **superior by means of RCTs**
- There is **no evidence demonstrating a singular component of any NPWT complete system is more important** in Wound Care than any of the others



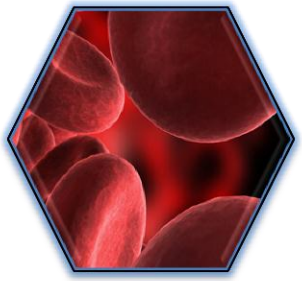
Invia® Negative Pressure Wound Therapy

- **Equivalent Safety and Efficacy as Standard of Care**
  - Small, portable, **lightweight**
  - **Safety** alarms
  - Data tracking capabilities

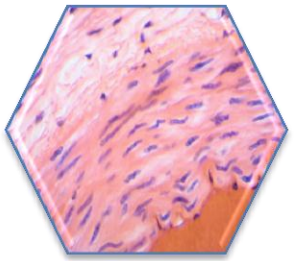
- **Clinical Package to support claims**
  - **Clinical studies**
    - Supporting benefits of foam and gauze based NPWT
  - Case Studies

- **Dressing Details**
  - **Choice** of dressing interface
    - Comfort of foam based NPWT
    - Benefits of gauze based NPWT
  - Offering flexibility in your clinical care

PartnerFirst™



Creates a moist wound environment[2]



Promotes perfusion[3]

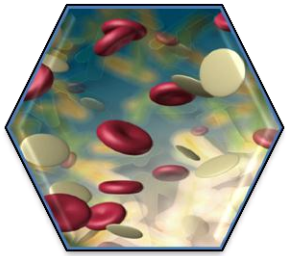
Draws wound edges together[2]

Effects of NPWT

Removes exudate and reduces edema[3]

Removes potentially infectious material from the healing area[3]

Promotes granulation tissue formation[3]



Invia® NPWT Clinical Evidence

Conclusion	Citation
• This case series demonstrates that a new ultra-portable device** can be used effectively on the majority of wounds for which NPWT is indicated and in all care settings. • A new device that promotes freedom and mobility helps patients resume normal daily activities which in turn improves patient care. • Patients found the system to be light, portable, easy to use and comfortable. They were very satisfied with the outcomes of this new solution.	Bowe M, Watson P, Tucker H, Moore C, Paglinawan R. A case series featuring a new NPWT device well suited for Home Healthcare. Presented at the Annual Symposium on Advanced Wound Care (SAWC) Spring, April 24 – 26, 2043, Orlando, FL, USA.
• A prospective case series, subcutaneous infections after median laparotomy for colorectal surgery were treated by NPWT with a PHMB gauze system and finally closed by secondary suture. • Our hypothesis was that NPWT provides shorter treatment time, minimal painas well as cost savings for the total treatment when compared to standard treatment (moist to-dry) dressing with gauze plus 0.04% PHMB solution. • Conclusion: PHMB gauze under NPWT proved to be a powerful system for treating SSI, provided a comfortable dressing that was noted to be in a “minimal pain level range” during dressing changes, and lowered overall treatment time and costs.	Koppes P, Krohs U, Mares A, Harlacher S, Bowe M, Paglinawan R, Marquardt C. Secondary suture in complication management of subcutaneous surgical site infections after colorectal surgery: A prospective case series using NPWT with PHMB gauze. Presented at the Annual Symposium on Advanced Wound Care (SAWC) Spring, April 24 – 26, 2043, Orlando, FL, USA.
• An ultra-portable NPWT device* was evaluated on three patients within the San Antonio Military Medical Center (SAMMC) and the Wilford Hall Medical Center (WHMC). • The cases demonstrate that a new ultra-portable personal NPWT device can be used effectively on the majority of wounds for which NPWT is indicated across the continuum of care; from the peri-operative period to home. • By using the new ultra-portable personal NPWT device*, the need for multiple NPWT systems throughout the various care settings is circumvented, thus changing the way NPWT systems are typically applied in practice today.	Bowe M, Chambers J, Miller Q, Ferguson E, Foulk R, Sinski S, Cantu J, Flowers A, Brower G, Paglianawan R. A paradigm shift in peri-operative NPWT. Presented at the Annual Symposium on Advanced Wound Care (SAWC) Fall, September 27 – 29, 2013, Las Vegas, NV, USA.

Invia® NPWT Clinical Evidence

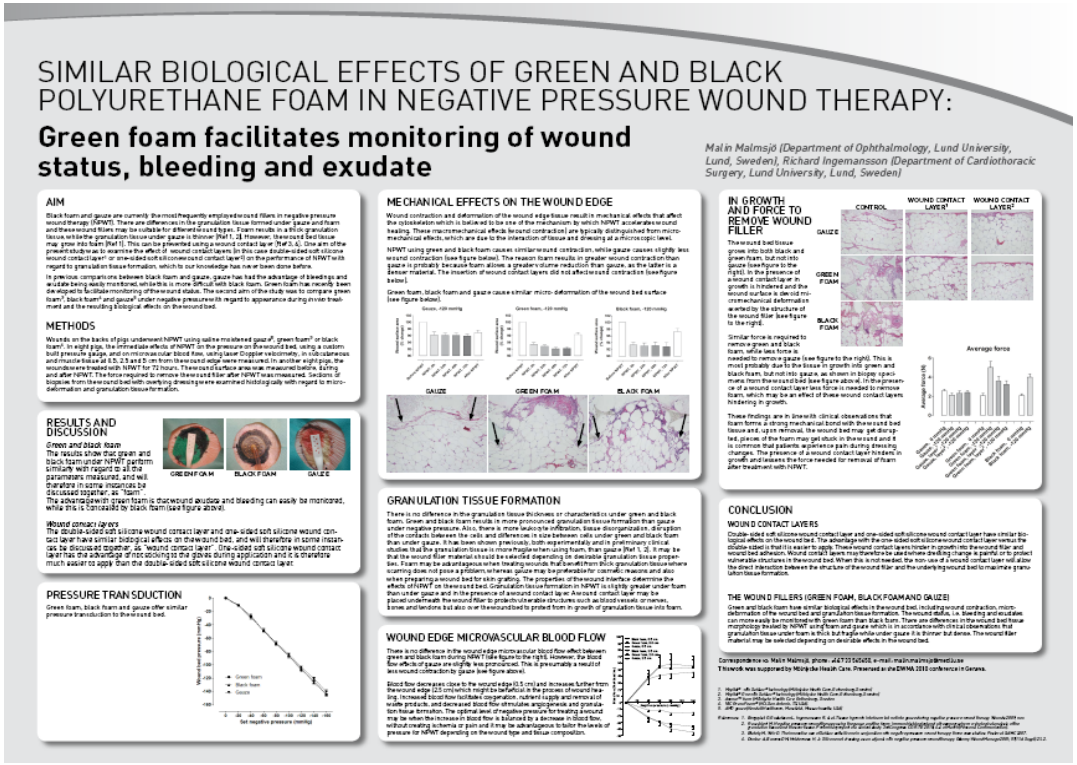
Conclusion	Citation
• Three patients with complicated post-operative wound infections treated with a new NPWT portable device* utilizing a sequential therapy program utilizing foam and gauze. • Demonstrated that the use of the new portable pump provided the possibility to discharge mobile patients managed with the sequential NPWT regimen and to perform dressing changes and secondary suture in the ambulatory care setting. • Demonstrated the usefulness of this small and portable pump in the successful treatment of wounds in a variety of healthcare settings.	Koppes P, Harlacher S, Bowe M, Paglinawan R, Marquardt C. Complex wounds: A new portable NPWT pump efficiently supports wound healing. Presented at the 26th Annual Clinical Symposium on Advanced Wound Care Spring/Wound Healing Society (SAWC Spring/WHS), May1-5, 2013 Denver, CO. USA.
• Green foam and black foam have similar biological effects on the wound bed. • Bleeding and exudate can be more easily monitored when using green foam or gauze. • Differences in the wound bed tissue morphology when using foam or gauze plus NPWT support clinical observations that granulation tissue under foam is thick but fragile, whereas that under gauze is thinner but denser.	Malmsjo M, Ingemanson R. Green foam, black foam or gauze for NPWT: effects on granulation tissue formation. Journal of Wound Care. June 2011; 20(6): 296-301.
• Compared to standard wet-to-dry gauze dressings with PHMB solution, NPWT therapy provides an inexpensive tool for lowering the total treatment costs. • PHMB gauze under NPWT proved to be a powerful system for treating SSI, providing a comfortable dressing that was noted to be in the minimal pain level range during dressing changes and lowered overall treatment time and costs.	Marquardt C, Koppes P, Krohs U, Bil E, Schiedeck Th, Paglinawan R, Simon M. NPWT with PHMB gauze for the treatment of surgical site infections after median laparotomy saves total treatment costs. Presented at the 24th Annual Clinical Symposium On Advanced Wound Care /Wound Healing Society (SAWC /WHS), April 14-17,2011 Dallas, TX,US
• A prospective single arm controlled study was started, based on the hypothesis that NPWT* with a PHMB gauze*** [1, 2, 3] on Surgical Site Infection (SSI) cases followed by secondary sutures for wound closure, provides a comfortable dressing and cosmetically good results.	Marquardt C, Krohs U, Bil E, Schiedeck Th, Paglinawan R, Simon M. Surgical site infections after median laparotomy treated with NPWT and PHMB gauze. Presented at the 24th Annual Clinical Symposium On Advanced Wound Care /Wound Healing Society (SAWC /WHS), April 14-17,2011 Dallas, TX,US.

Invia® NPWT Clinical Evidence

Conclusion	Citation
• In this case series, NPWT system* with PHMB gauze interface*** was evaluated to treat these difficult postoperative situations, which could not be re-operated. Necessary stoma pouches further complicated dressing application. • The NPWT system* with PHMB gauze*** showed an outstanding capacity in treating challenging postoperative abdominal wounds with intestinal fistula. During treatment patients were mobile with a high degree of comfort. • For the three patients, the therapy revealed its efficacy and met clinician‘s expectations.	Marquardt C, , Krohs U, Bil E, Schiedeck Th, Jurczok A Paglinawan R, Simon M. Challenge in Wound Care: Management of the Open Abdomen with Intestinal Fistula and Stoma. Presented at the 23rd Annual Symposium on Advanced Wound Care & Wound Healing Society (SAWC/WHS), Orlando, Florida, USA, April 17-20, 2010
• A retrospective analysis of archival data from wounds of 55 patients treated with a gauze based NPWT system was subjected to data quality assessment and statistical analysis. • On average, wounds were 62.7% of their initial areas and 24.28% or their initial volumes at the endpoint of therapy. • Demonstrated the gauze based NPWT system is effective in accelerating wound healing.	Ammar A, Paglinawan R, Chariker M, Simon M. Healing rates in patients receiving negative pressure wound therapy. Presented at the 22nd Annual Clinical Symposium on Advanced Wound Care /Wound Healing Society (SAWC /WHS), April 26-29, 2009 Dallas, TX. US.
• A comparison of various existing dressing types in combination with a negative pressure wound therapy system and study the influence on both wound closure and granulation tissue formation in wounds of porcine. • Results suggest that healing is taking place with each one of the dressings used in combination with NPWT on porcine wound model.	Paglinawan R, Colic M, Simon M. A comparative of various dressings coupled to a negative pressure system to study effects on wound healing. Presented at the 22nd Annual Clinical Symposium on Advanced Wound Care /Wound Healing Society (SAWC/WHS), April 26-29, 2009 Dallas, TX. US.

In-vitro Studies

M Malmsjö, Ingemansson R. Similar biological effects of green and black polyurethane foam in negative pressure wound therapy: green foam facilitates monitoring of wound status, bleeding and exudate.



SIMILAR BIOLOGICAL EFFECTS OF GREEN AND BLACK POLYURETHANE FOAM IN NEGATIVE PRESSURE WOUND THERAPY:

Green foam facilitates monitoring of wound status, bleeding and exudate

Malin Malmsjö (Department of Ophthalmology, Lund University, Lund, Sweden), Richard Ingemansson (Department of Cardiothoracic Surgery, Lund University, Lund, Sweden)

AIM

METHODS

RESULTS AND DISCUSSION

PRESSURE TRANSDUCTION

MECHANICAL EFFECTS ON THE WOUND EDGE

GRANULATION TISSUE FORMATION

WOUND EDGE MICROVASCULAR BLOOD FLOW

IN GROWTH AND FORCE TO REMOVE WOUND FILLER

CONCLUSION

Poster presented at EWMA, Geneva May 2010

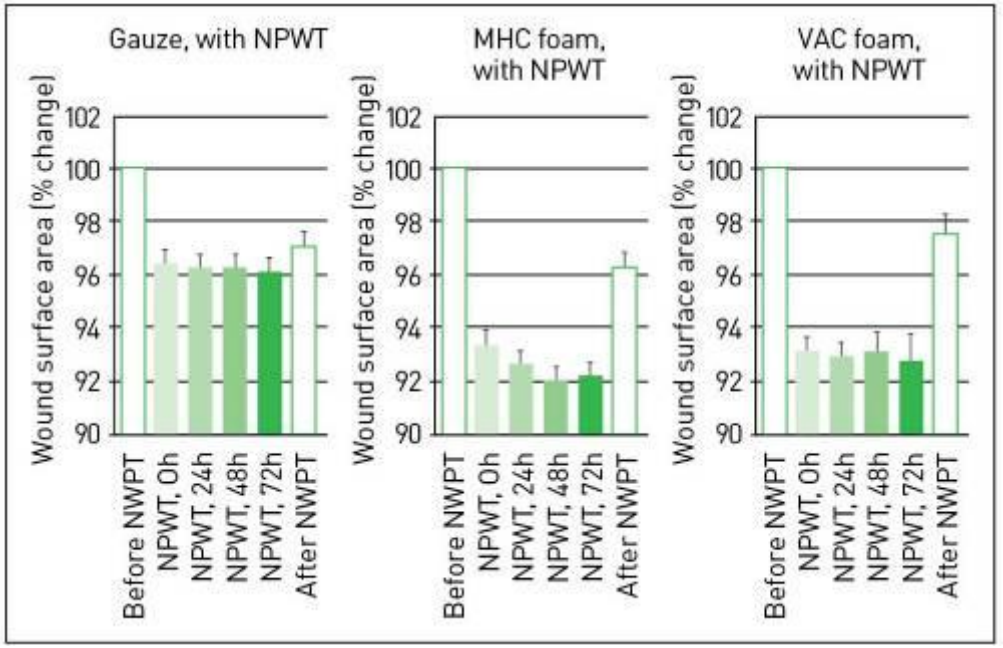
Parameters assessed

The measures compared for each of the three wound filler types in the two animal studies included:

- **Mechanical effects (contraction)**
- **Quantity & quality of granulation tissue with different fillers**
- **Wound bed tissue in-growth into the wound filler**
- **Pressure transduction**
- **Blood flow in the wound bed**

Results: Wound contraction

- Wound contraction was slightly greater for foam (both MHC & V.A.C.) than for gauze
- Percentage changes in wound surface area were similar



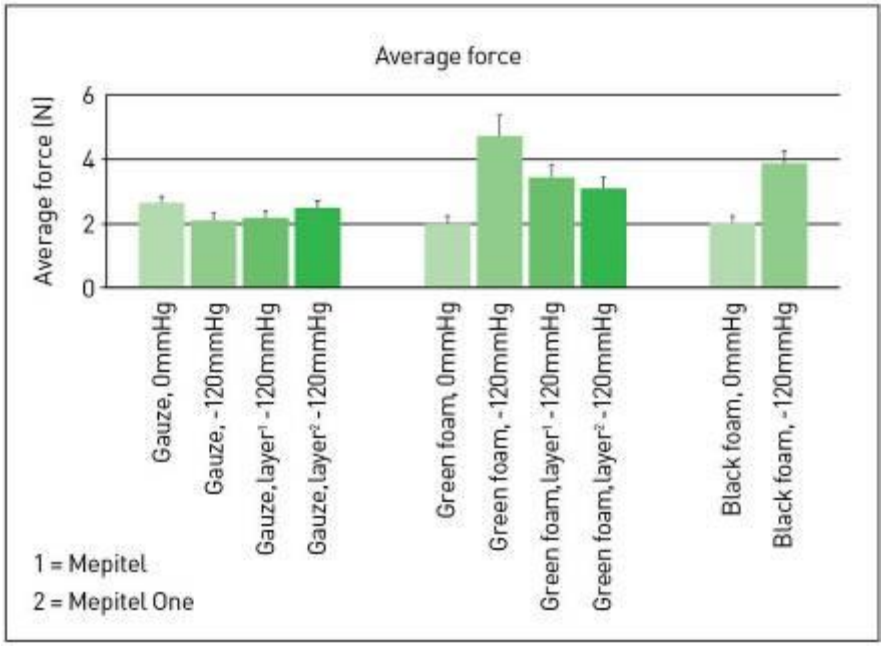
Results: Granulation tissue formation

- Granulation tissue formation is slightly greater under foam than under gauze and in the presence of a wound contact layer (in this case Mepitel and Mepitel One)
- Degree of granulation tissue similar for both MHC Avance foam and V.A.C. Granufoam

Malin Malmsjö, MD, PhD (in press)

Results: Tissue in-growth

- Wound bed tissue grows into foam but not into gauze
- Reflected in findings of case studies showing gauze to be easier to remove
- Removal of AMD gauze does not disrupt the wound bed and may lessen patient pain during dressing changes.
- The presence of Mepitel[1] + Mepitel One[2] hinders in-growth and lessens the force needed for removal of foam in NPWT



COMPLEX WOUNDS: A NEW PORTABLE NPWT PUMP EFFICIENTLY SUPPORTS WOUND HEALING

P. Koppe [1], S. Herlacher [1], M. Bowe [2], R. Paglinawan [3], C. Marquardt [1]
[1] Department of General and Visceral Surgery, Ludwigsburg Hospital, Germany
[2] Medela Healthcare, McHenry, U.S.A.
[3] Medela Healthcare, Baar, Switzerland

Introduction

The Department of General and Visceral Surgery at the Ludwigsburg Hospital has 28 beds and covers almost all visceral operations except organ transplantation. The effective treatment of postoperative wound infections is an essential element in patient care. To discharge a patient with a closed wound, we have quality of life and reduced total treatment costs. The Ludwigsburg Clinic's gauze based SuS regulated pressure wound therapy (NPWT) program (3 times NPWT dressing changes, each over 3 days, then secondary suture) was proven to be effective (over 80% healing rate) and became part of our hospital routine [1]. Due to the Diagnosis-Related-Groups (DRG) system in Germany, one key point in economic patient management is shifting in patient's into an out-patient therapy regimen.

Along with the SuS NPWT regimen, sequential NPWT may also be applied to patients presenting with complicated wounds requiring longer treatment times.

Here, we show three patients with complicated post-operative wound infections treated with a novel NPWT pump's device* utilizing a sequential therapy program.

We demonstrate that the use of the new portable pump provides the possibility to discharge mobile patients managed with the sequential NPWT regimen and to perform dressing changes and secondary suture in the ambulatory care setting.

Methods

A new portable NPWT pump* was evaluated on three patients in our hospital routine. Wound management was in the hands of our established and specialized wound team. The new portable NPWT pump* was used in conjunction with a sequential dressing protocol which included the application of PU foam post operation/debridement to guarantee good wound management and cassettes of foam change (changed every 2 – 3 days after the first high exudate wound healing phase). During later bed-side NPWT dressing changes, a gauze based system with equal effects, which is easy and quick to apply was used (change of every 2 – 3 days) for further wound conditioning. None of the patients presented with contraindications such as:

- Malignancy of the wound
- Untreated osteomyelitis
- Non-enteric and unexplored fistula
- Necrotic tissue with eschar present
- Exposed vessel/bone
- Exposed nerves
- Exposed anastomotic site of blood vessels or bypasses
- Exposed organs

Results

The new portable NPWT device* was utilized on various wound types to help understand the range of indications for which the new portable NPWT system* may be used. It was also of interest to observe if the new portable NPWT system* can clinically compete against other portable pumps available on the market. In order to address such questions, a questionnaire for both the user and the patients was developed and applied. Details of the presented cases of patients in this case series with complicated wounds (a combination of in-patient and out-patient cases) demonstrate the great spectrum of wounds which may be safely treated with the new portable NPWT device*.

Case Description: Patient 1 (complete therapy as outpatient)

42 year old male patient (BMI 30.5) underwent surgery for a left groin explicit abscess and sepsis bleeding in July 2010. Postoperatively, the patient developed an open abdominal wound, which was treated with NPWT until August 2010. A very large hernia was closed by implantation of an IPOM mesh grafts in March 2011. A persistent fistula was excised in February 2012 and a postoperative infection was treated with NPWT on an ambulatory basis. NPWT was initiated for infection control and induction of granulation tissue formation on the exposed mesh and graft, with the aim of secondary healing.

- 1st NPWT dressing with gauze from June 09 – 12 March 2012 (125 mmHg)
- 2nd NPWT dressing with gauze from 12 – 16 March 2012 (125 mmHg)
- 3rd NPWT dressing with gauze from 16 – 20 March 2012 (100 mmHg)
- 4th NPWT dressing with gauze from 20 – 23 March 2012 (175 mmHg)
- 5th NPWT dressing with gauze from 23 – 27 March 2012 (175 mmHg)

All 5 cycles of NPWT without wound contact layer. 5 dressing kits and 5 canisters were used during all therapy. With achievement of good granulation and wound closure using the NPWT was terminated on the 22nd of March 2012 with ongoing conservative treatment and no concerns mid-wound dressings with hydrofiber dressings.

Case Description: Patient 2 (both inpatient and outpatient)

74 year old male patient with a long standing wound complication leading 10 months. The patient underwent surgery for an umbilical hernia in January 2011. Postoperatively, he developed peritonitis due to a small bowel perforation and had open abdominal wound was treated with NPWT. An infection of a mesh graft persisted and the abdomen healed secondarily. After one year the patient returned to our hospital for fistula resection and closure of a large abdominal hernia. We performed an adhesiolysis and resection of the small bowel segment with the fistula, and implantation of an onlay mesh for hernia repair in April 2012. Postoperatively, the wound healed, but a fistula persisted in the lower abdomen. Revision showed an aberrant complete infection of the mesh implant, which was treated in the Ludwigsburg hospital by debridement and NPWT from May 2012 until June 2012.

After the wound was partially closed and a gauze based NPWT system could be used, the patient was discharged from the hospital and treated on an ambulatory base with the convenience of the new portable NPWT device* treated at 175 mmHg intervals. From the 1st June 2012 until 13th July 2012 (6 NPWT dressing changes were performed. At discharge date, all NPWT, the mid-wound completely covered by granulation tissue and the wound was small enough to be treated with conventional antimicrobial dressings.

Case Description: Patient 3 (complete therapy as inpatient)

64 year old female patient (BMI 32.8) underwent lung resection on the left breast for breast cancer, earlier resection of the lymph nodes and IORT (intraoperative radiotherapy) on 18 January 2012. Postoperatively, she developed a hematoma and wound infection with fistula at the earlier wound, which was treated with local treatment for 3 months without success. Debridement and NPWT was initiated for induction of granulation tissue formation and excellent management with the aim of secondary suture closure.

Other comorbidities include a cardiac pacemaker for tachyarrhythmia, the aortic regurgitant Rheumatic tumor, insulin dependent diabetes mellitus, hypertension and high cholesterol level.

- 1st NPWT dressing with gauze from June 12 – 15 March 2012 (100 mmHg)
- 2nd NPWT dressing with PHMB gauze from 15 – 19 March 2012 (100 mmHg)
- 3rd NPWT dressing with PHMB gauze from 19 – 21 March 2012 (100 mmHg)
- 4th NPWT dressing with gauze from from 21 – 22 March 2012 (100 mmHg)

All cycles of NPWT with soft wound contact layer. 4 dressing kits and 2 canisters were used during all therapy. The aim of NPWT was secondary suture, which could not be achieved due to secondary infection of the therapy by the patient after developing cardiac problems not connected with NPWT.

Conclusions

The antibody effect of foam with its foam cell layer and gauze under NPWT was previously shown [2, 3]. Here we demonstrate a unique sequential dressing protocol applied on patients with complicated surgical wounds in elderly, co-morbid patients with the sequential application of both foam and gauze dressings under NPWT. The sequential NPWT dressing protocol appeared to have supported wound healing. Moreover, by using the new portable NPWT device* together with the sequential dressing protocol, data establishes the usefulness of this small and reliable pump in the successful treatment of wounds in a variety of healthcare settings. These cases show, for the first time, a new portable NPWT system* to be highly useful in supporting wound healing in complicated wounds and in a variety of care settings. Clinicians also experience in the mobility of these patients where normal function during their daily lives is desired, thereby offering a new tool for modern day NPWT and improved patient care.

Literature
1. Wanner M. C., Koppe P., Kohn G., Bill R., Schaefer Th., Paglinawan R., Erben M.: NPWT with PHMB Gauze for the treatment of Surgical Site Infections after Median Laparotomy: a new Treatment Option. Symposium of Advanced Wound Care & Wound Healing Society (SAWC/WHS) 16th Annual Symposium, Dallas, Texas, USA, April 14 – 17, 2011
2. Malmsjö M, Ingemansson R, Martin R, Huddleston P. Negative pressure wound therapy using gauze or open cell polyurethane foam: cellular early effects on proteases in bone marrow and tissue granulation in an experimental porcine wound model. Wound Repair Regen. 2009 Mar-Apr; 17(2): 235-8
3. Wanner M. C., Paglinawan R., Schaefer Th.: Gauze versus Foam for topical negative pressure wound therapy (NPWT): a prospective subsequent wound study one after abdominal sepsis. First clinical observations. 18th Conference of the European Wound Management Association in Lucern, Portugal, 14 – 16.06.2006

Notes:
* "mollyMolution" NPWT System (Medela AG, Baar, Switzerland)
** Avance® NPWT System (Smith&Nephew Health Care AB, Gothenburg, Sweden)

Patient de-identification is implemented in all photographs.

The primary research in this study has been investigating various sub-atmospheric pressure settings in the management of wounds including high-pressure settings. There is applied pressures are within our clinical experience.

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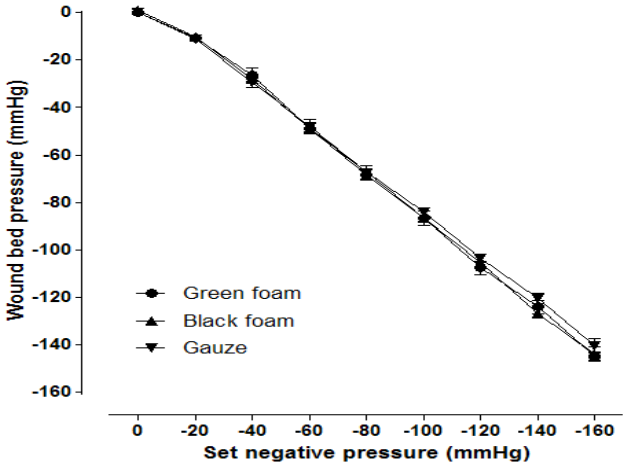
Acknowledgements
The support of Medela AG (Lüchtenswerk, Kürt Baar, Switzerland) is very much appreciated.

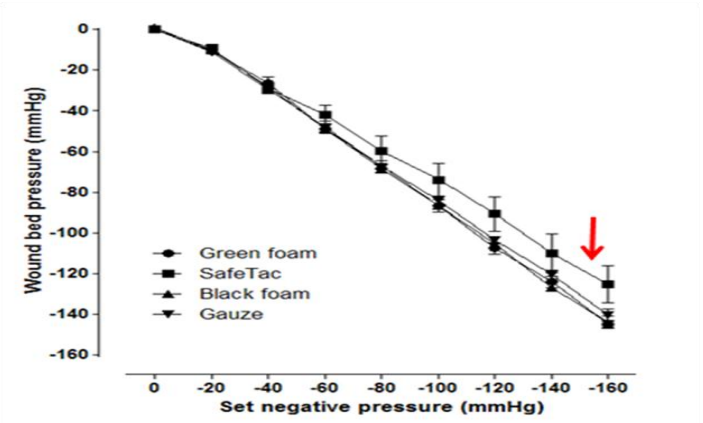
Presented at the 24th Annual Symposium on Advanced Wound Care & Wound Healing Society (SAWC Spring/WHS), May 1 – 5, 2012, Denver, CO., USA.

This poster is in this poster will be presented at the upcoming WOCN 44th Annual Conference (June 02-06, 2012).

Results: Pressure transduction

- Optimal pressure transduction with MHC Avance foam, KCI V.A.C. Granufoam, and gauze
- All three fillers were comparable
- When using Safetac technology (Mepitel and Mepitel One) wound bed pressures achieved were reduced

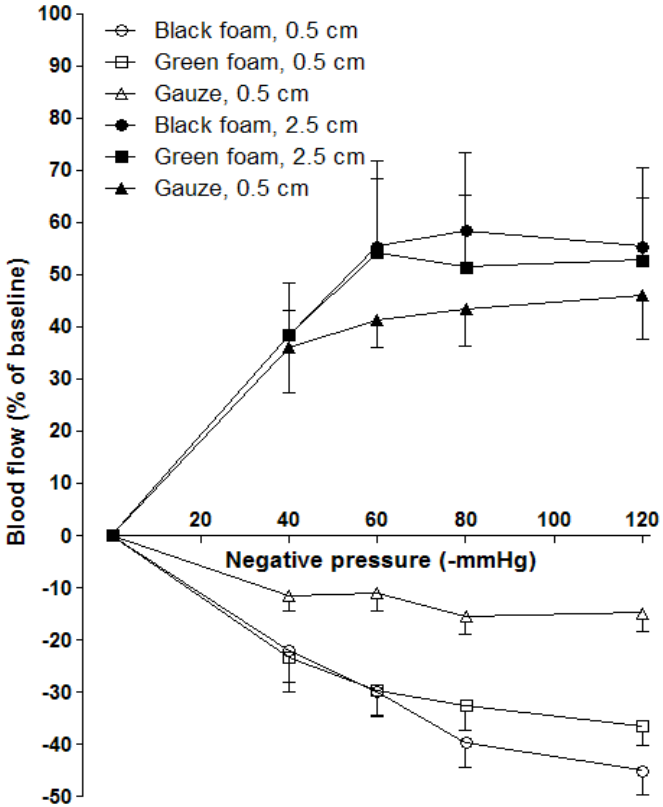




Malin Malmsjö, MD, PhD (in press)

Results: Microvascular blood flow in the wound edge

- Observations regarding blood flow were similar for MHC Avance foam and KCI V.A.C. Granufoam
- Gauze had slightly less pronounced blood flow effects, especially at 0.5 cm from the wound edge
- Increased blood flow facilitates oxygenation, nutrient supply and removal of waste products
- Decreased blood flow stimulates angiogenesis and granulation tissue formation



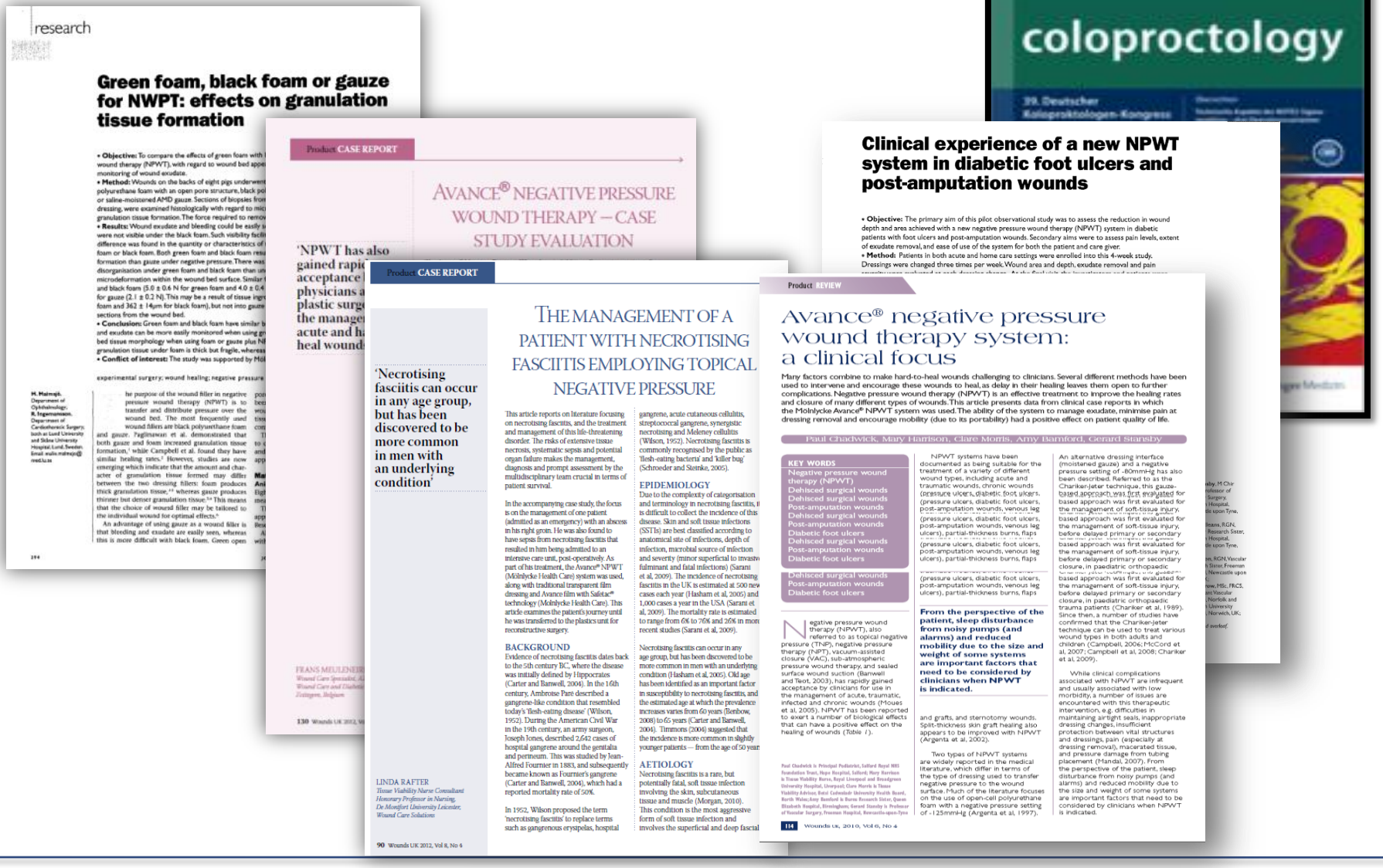
Avance® NPWT Clinical Evidence

Conclusion	Citation
• Pilot observational study on 16 patients with diabetic foot ulcers • Indicated that use of the new NPWT system can be expected to have a positive effect on the healing of post-amputation wounds and foot ulcers in patients with diabetes. • Demonstrated that the system is easy to use, effectively controls exudate, and minimizes pain and inconvenience for patients being treated with NPWT.	Stansby G, Wealleans V, Wilson L, Morrow D. Clinical experience of a new NPWT system in diabetic foot ulcers and post-amputation wounds. Journal of Wound Care. November 2010; 19(11.
• This poster describes the results of a study that set out to assess the effectiveness of a new negative pressure wound therapy (NPWT) system* in the treatment of a variety of different wound types in both hospital and home care settings. • This case study series highlights that the NPWT system is a highly flexible and portable means of applying negative pressure to a variety of different wound types.	Pritchard B, Cadwaladr B. Clinical experience with a new negative pressure wound therapy system in the treatment of a variety of different wound types. University Health Board, Wrexham Maelor Hospital, Wrexham, United Kingdom. 2011.
• This poster describes a new system that can be used to provide continuous and/or intermittent negative pressure (-60 to -200mmHg). The dressing kits supplied with the NPWT system give clinicians the option of either foam dressings or AMD gauze dressings (AMD gauze), with/without an atraumatic wound contact layer** which can be used underneath the wound dressings to promote patient comfort. • This case study series highlights that the NPWT system is a highly flexible and portable means of applying negative pressure to dehisced surgical wounds.	Harrison M. Case study evaluations of a new negative pressure wound therapy system in the treatment of dehisced surgical wounds. Royal Liverpool and Broadgreen University Hospital Trust, Liverpool, United Kingdom. 2011.
• This poster outlines the results of a multicentre case series that was undertaken to evaluate the performance of a new negative pressure wound therapy (NPWT) system a in the management of a variety of complex, hard-to-heal wound types, all of which are associated with significant disability and mobility as well as having a considerable impact on health care resources. • The new NPWT system is a highly flexible and portable means of applying negative pressure to a variety of different wound types	Chadwick P, Bamford A, Harrison M, Pritchard B. Multicentre clinical evaluation of a new negative pressure wound therapy system in the treatment of complex, hard-to-heal wounds. Salford Royal NHS Foundation Trust, Hope Hospital, Salford, UK. University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK. Royal Liverpool and Broadgreen University Hospital Trust, Liverpool, UK.Betsi Cadwaladr University Health Board, Wrexham Maelor Hospital, Wrexham, UK. 2011

Avance® NPWT Clinical Evidence

Conclusion	Citation
• This poster reports on the results of a case study series that was undertaken to evaluate the performance of a new NPWT system* in the management of foot ulcers associated with diabetes and/or neuropathy. • The findings of the case study series outlined in this poster indicate that the new system is highly flexible, portable and effective, although larger clinical studies need to be undertaken in order to confirm this.	Chadwick P, Haycocks S, Watts K. Use of a new negative pressure wound therapy system in the treatment of foot ulcers: a case study series Salford Royal NHS Foundation Trust, Hope Hospital, Salford, UK. 2011.
• This poster reports on the results of a case series that was undertaken to evaluate the performance of a new NPWT systema in establishing split-thickness skin grafts during the management of burn wounds of varying severity. • The new NPWT system is a flexible, portable and effective system in the management of burn wounds of varying severity.	Bamford A. Management of burn wounds with a new negative pressure wound therapy system. University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK. 2011
• This article has outlined the most relevant literature available on the management and treatment of necrotising fasciitis. • Demonstrates the effectiveness of the Avance topical negative system. The management of these complex wounds requires a great deal of collaboration between members of the multidisciplinary team and the company. • The Avance Film with Safetac technology delivers a pain-free dressing change towards the end of the patient care pathway.	Rafter L. The management of a patient with necrotizing fasciitis employing topical negative pressure. Wounds UK 2012, Vol 8, No 4
• Product review article and case studies • The data generated from laboratory and clinical evaluations of the Mölnlycke Avance NPWT system indicate that it is clinically effective (i.e. it is a single system that can be applied to a wide range of wound types in both hospital and home settings) and is easy to use (i.e. it is lightweight and portable).	Chadwick P, Bamford A, Harrison M, Pritchard B, Morris P, Stansby G. Avance® negative pressure wound therapy system: a clinical focus. Wounds uk, 2010, Vol 6, No 4.

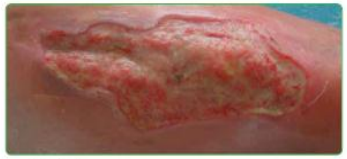
Avance Publications: Clinical Evidence 2012-13

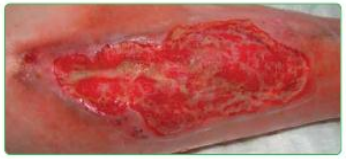


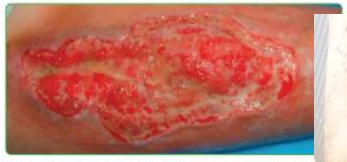
Proven Efficacy On All Wounds For Which NPWT Is Indicated

Skin Graft

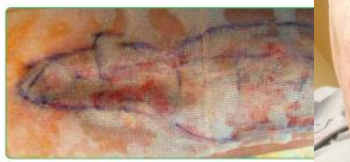

Leg wound with bone is exposed


Day 1 (10/12/2008): Gauze-based NPWT initiated in preparation for skin grafting

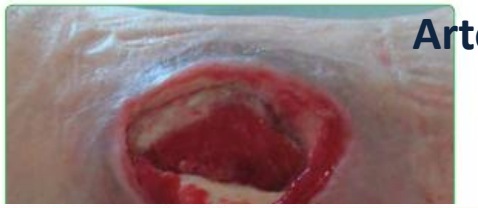

Day 16 (26/12/2008): Post-wound cleansing and gauze-based NPWT dressing change


Day 26: (05/01/2009): Post-wound cleansing and gauze-based NPWT dressing change


Day 72 (20/02/2010): Skin graft applied, gauze-based NPWT initiated to aid skin graft uptake


Day 72 (20/02/2010): Non-adherent dressing applied on top of skin gr and then gauze-based NPWT


Day 75 (23/02/2010): Post gauze-based NPWT d progression of skin graft



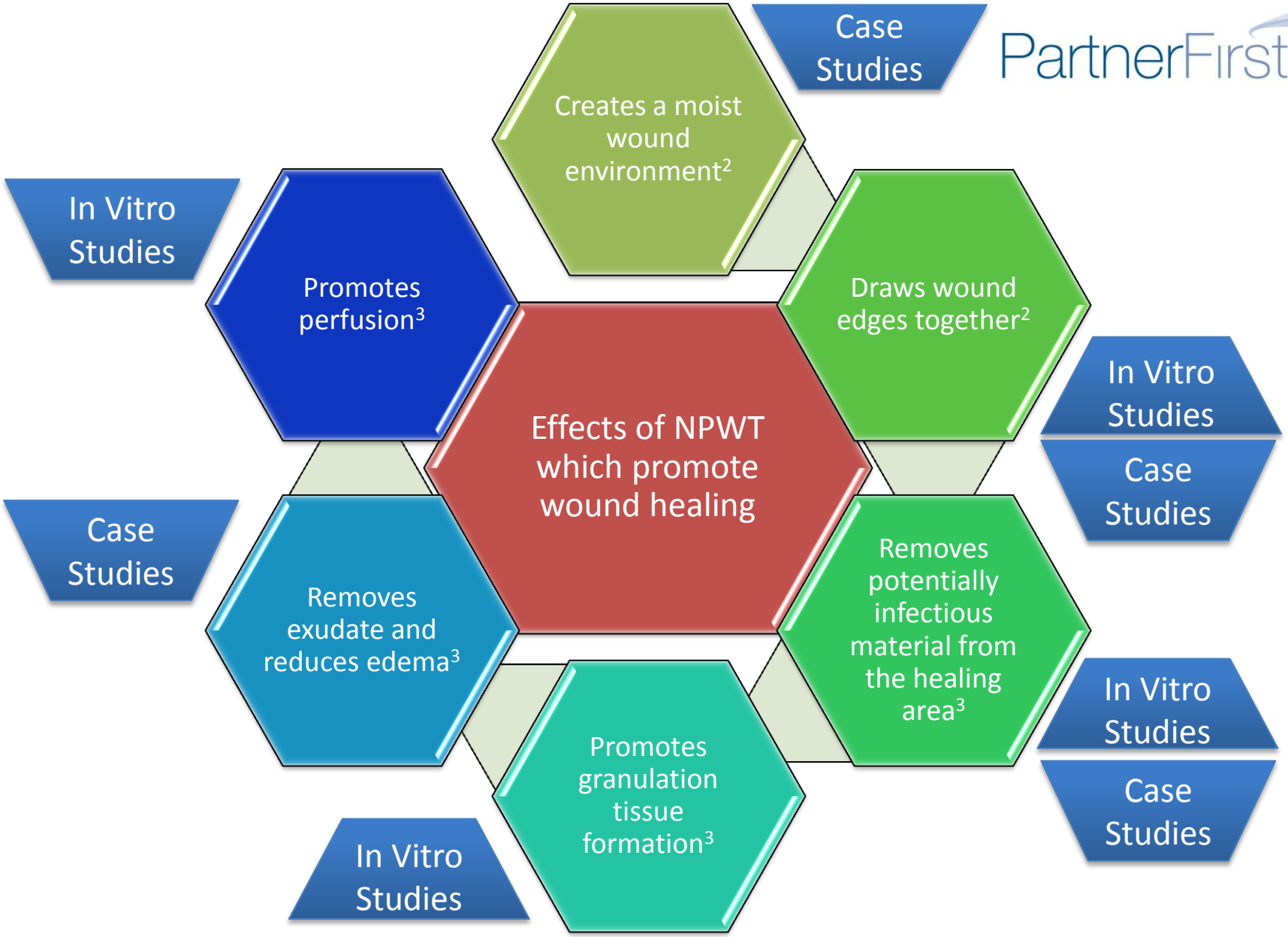

d NPWT discontinued

Day 1 (18/05/2009): Post debridement, and initiation of gauze-based NPWT for Stage III sacral pressure ulcer


14/10/2009: Patient follow up, post gauze-based NPWT and epithelialisation therapy

Figure 2: Dressing change demonstrating the extent of tissue damage in the groin.


Figure 3: Another example of the full extent of tissue damage.


Case Studies
Creates a moist wound environment[2]
In Vitro Studies
Promotes perfusion[3]
Draws wound edges together[2]
In Vitro Studies
Case Studies
Effects of NPWT which promote wound healing
Case Studies
Removes exudate and reduces edema[3]
Removes potentially infectious material from the healing area[3]
In Vitro Studies
Case Studies
Promotes granulation tissue formation[3]
In Vitro Studies

medela

NPWT System
Clinical Evidence Summary

Invia® Motion™ Invia® Liberty™

Precious life – Progressive care

Invia® NPWT System

Clinical and Case Studies

Negative Pressure Wound Therapy (NPWT) uses sub atmospheric pressure to expedite wound healing and is treatment postulated to be an effective promoter of wound healing in a variety of acute and chronic wounds. The effects of NPWT include: create a moist wound environment; draw the wound edges together; remove potentially infectious material from the healing area; promote granulation tissue formation; remove exudate and reduce edema; and promote perfusion.[1,2] The clinical effects of NPWT have been elucidated through animal and in vivo model studies as well as multiple clinical research and case studies. Thus far, the absence of head-to-head comparison studies and clinical research on comparison studies of NPWT systems versus a common comparator, demonstrate the inability to identify a significant therapeutic distinction between one NPWT system or component over another.[1] This document includes the clinical and case studies Medela and Mölnlycke Health Care, have conducted to demonstrate the clinical safety and efficacy of our NPWT System.

1. Agency for Healthcare Research and Quality. Negative pressure wound therapy devices: technology assessment report. Available at:www.ahrq.gov/Clinic/ta/negpresswtd. Accessed May 2012.
2. Banwell P, Musgrave M. Topical negative pressure therapy: mechanisms and indications. Int Wound J 2004;1:95-106.

Invia® Liberty™ NPWT Clinical Evidence

Citation	Key Points	Study Type	Wound Etiology									Wound Filler	
			Surgical	Trauma	Burn	Flap/Graft	Enteric Fistula	Diabetic Foot	Pressure Ulcer	Venus Ulcer	Arterial Ulcer	Foam	Gauze
Koppes P, Krohs U, Mares A, Harlacher S, Bowe M, Paglinawan R, Marquardt C. **Secondary suture in complication management of subcutaneous surgical site infections after colorectal surgery: A prospective case series using NPWT with PHMB gauze.** Presented at the Annual Symposium on Advanced Wound Care (SAWC) Spring, April 24 – 26, 2043, Orlando, FL, US.	• Subcutaneous infections after median laparotomy for colorectal surgery were treated by NPWT with a PHMB gauze system and finally closed by secondary suture. • Hypothesis: NPWT provides shorter treatment time, minimal pain as well as cost savings for the total treatment when compared to standard treatment (moist-to-dry) dressing with gauze plus 0.04% PHMB solution. • Conclusion: PHMB gauze under NPWT proved to be a powerful system for treating SSI, provided a comfortable dressing that was noted to be in a "minimal pain level range" during dressing changes, and lowered overall treatment time and costs.	Prospective case series	●										●
Malmsjo M, Ingemanson R. **Green foam, black foam or gauze for NPWT: effects on granulation tissue formation.** Journal of Wound Care. June 2011; 20(6): 296-301.	• Green foam and black foam have similar biological effects on the wound bed. • Bleeding and exudate can be more easily monitored when using green foam or gauze. • Differences in the wound bed tissue morphology when using foam or gauze plus NPWT support clinical observations that granulation tissue under foam is thick but fragile, whereas that under gauze is thinner but denser.	Porcine wound model										●	●
Marquardt C, Koppes P, Krohs U, Bil E, Schiedeck Th, Paglinawan R, Simon M. **NPWT with PHMB gauze for the Treatment of surgical site infection after median laparotomy saves total treatment costs.** Presented at the 24th Annual Clinical Symposium On Advanced Wound Care/Wound Healing Society April 14-17,2011 Dallas, TX,US.	• Compared to standard wet-to-dry gauze dressings with PHMB solution, NPWT therapy provides an inexpensive tool for lowering the total treatment costs. • PHMB gauze under NPWT proved to be a powerful system for treating SSI, providing a comfortable dressing that was noted to be in the minimal pain level range during dressing changes and lowered overall treatment time and costs.	Prospective case series	●										●
Wyndam-White C, Rosset C, Paglinawan R, Reed S. **The use of gauze based NPWT system to assist wound closure.** Presented at the Annual (SAWC) Spring, April 17– 20, 2010, Orlando, FL, US	• Three patients with chronic wounds were treated with a gauze based NPWT system to assist granulation formation and wound closure. • All wounds responded well in all three patients.	Case series				●			●				●

Invia® Motion™ NPWT Clinical Evidence

Citation	Key Points	Study Type	Wound Etiology									Wound Filler	
			Surgical	Trauma	Burn	Flap/Graft	Enteric Fistula	Diabetic Foot Ulcer	Pressure Ulcer	Venus Ulcer	Arterial Ulcer	Foam	Gauze
Bowe M, Watson P, Tucker H, Moore C, Paglinawan R. **A case series featuring a new NPWT device well suited for Home Healthcare.** Presented at the Annual Symposium on Advanced Wound Care (SAWC) Spring, April 24 – 26, 2014, Orlando, FL, US.	• An ultra-portable device can be used effectively on the majority of wounds for which NPWT is indicated and in all care settings. • A device that promotes freedom and mobility helps patients resume normal daily activities which in turn improves patient care. • Patients found the system to be light, portable, easy to use and comfortable.	Case series	●					●				●	●
Bowe M, Chambers J, Miller Q, Ferguson E, Foulk R, Sinski S, Cantu J, Flowers A, Brower G, Paglianawan R. **A paradigm shift in perioperative NPWT.** Presented at the Annual Symposium on Advanced Wound Care (SAWC) Fall, September 27 – 29, 2013, Las Vegas, NV, US.	• An ultra-portable NPWT device was evaluated on three patients within the San Antonio Military Medical Center (SAMMC) and Wilford Hall Medical Center (WHMC). • Demonstrate that an ultra-portable personal NPWT device can be used effectively on the majority of wounds for which NPWT is indicated across the continuum of care; from the peri-operative period to home. • By using the ultra-portable personal NPWT device, the need for multiple NPWT systems throughout the various care settings is circumvented, thus changing the way NPWT systems are typically applied in practice today.	Case series	●					●				●	
Koppes P, Harlacher S, Bowe M, Paglinawan R, Marquardt C. **Complex wounds: A new portable NPWT pump efficiently supports wound healing.** Presented at the 26th Annual Clinical Symposium on Advanced Wound Care Spring/Wound Healing Society May1-5, 2013, Denver, CO. US.	• Three patients with complicated post-operative wound infections treated with a NPWT portable device utilizing a sequential therapy program utilizing foam and gauze. • Demonstrated that the use of the portable pump provided the possibility to discharge mobile patients managed with the sequential NPWT regimen and to perform dressing changes and secondary suture in the ambulatory care setting. • Demonstrated the usefulness of the portable pump in the successful treatment of wounds in a variety of healthcare settings.	Case series	●									●	●

Future