Prospective Randomized Evaluation of the Effect of Avance® Solo Negative Pressure Wound Therapy System or Optifoam® Gentle Post-Op Dressing on "High Risk" Closed Surgical Incisions; Freedom From Wound Complication Study

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CLINICAL IN MARKET EVALUATION PROTOCOL

EVALUATION NUMBER: CINPWT

EVALUATION TITLE: Prospective randomized evaluation of the effect of Avance® Solo Negative Pressure Wound Therapy System or Optifoam® Gentle Post-Op Dressing on “high risk” closed surgical incisions; freedom from wound complication study

PRODUCT: Avance® Solo Negative Pressure Wound Therapy System (Best Practices – Optifoam® Gentle Post-Op)

SPONSOR: Investigator Initiated

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DOCUMENT CONTROL

THIS ISSUE:	**Draft 5**	**05/10/2022**
PREVIOUS ISSUES:	**Draft 4**	**04/05/2022**
	Draft 3	**03/21/2022**
	Draft 2	**03/14/2022**
	Draft 1	**02/01/2022**

DOCUMENT CIRCULATION

APPROVAL AND AGREEMENT

I confirm that the evaluation product will be used in accordance with its licensed instructions for use

....

Date Evaluation Clinician Signature Name (Printed)

The evaluation Clinician confirms that IRB opinion has been sought and approval is:

- Full approval has been obtained

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…… ……. ……
Date Evaluation Clinician Signature Name (Printed)

If IRB approval is required, the evaluation clinician must submit the evaluation protocol to the IRB. If approval is required, the first patient will not be enrolled into the Clinical In-Market Evaluation until the local Molnlycke evaluation coordinator has been sent a copy of the approval letter in which the protocol are mentioned by name and number.

1 INTRODUCTION

1.1 RATIONALE

To determine if “high risk” surgical incisions develop healing complications within 21 days of surgery. High risk is defined as a standard incision in the “ high risk patient” (diabetes, obesity, poor anatomy, malnutrition). Or a “high risk incision” such as a foot and ankle incision, flap incision or major soft tissue resection with a large amount of dead space.

A healing complication is defined as the presence of at least one of these clinical scenarios: infection (superficial or deep), (evidenced by the prescription of oral antibiotics,(partial, superficial, or deep), or delayed healing (incision not 100% closed within 7 days of the first surgical procedure). Ongoing wound drainage from the incision after 96 hours, periwound erythema, minor dehiscence or major dehiscence.

The purpose of this study is to assess the efficacy of the FDA cleared device, Avance® Solo, an device that delivers negative pressure wound therapy to closed incisions (NPWTi), and to assess the number of healing complications that result from its use[1, 2], compared to the current hospital standard Optifoam® Gentle Post op Dressing (a silicone backed foam that is conformable, with a border that is waterproof, flexible and breathable for increased comfort, with a wear time of up to seven days). This foam is currently stocked by the operating rooms at Mount Sinai hospital and indicated for use in high risk wounds (although there is no data to support its usage).

Historically, the use of negative pressure wound therapy for surgical incisions can assist in the management of surgical incisions. There are thought to be at least 6 positive mechanisms of action; protects the incision from the external environment, removes surface drainage and lymphatic drainage, resists gaping through application of lateral tension, increase breaking strength of healed incisions, reduces seroma and haematoma fluid collections, reduces edema, improves perfusion compared to area not treated with NPWT.

Many papers (primarily single center, single arm and or underpowered studies have supported the use of closed incisional NPWT. Previous basic science research has shown that NPWTi has a significant impact on improved incisional outcomes. Some have been small studies such as Pachowsky et al (2011) Nuremberg, Germany, who ultrasounded total hip arthroplasty: 9 patients with iNPWT in place for 5 days vs. 10 patients with standard dressings. He showed a reduction in volume of periwound seromas.[3]

The largest study to date randomized the effect of NPWTi in 249 patient with 263 fractures. Groups were matched for different types of fracture. The average use of NPWT was for just 2.5 days and a statistically significant reduction in deep infection: 19.0 v 10.0% P = 0.049; and dehiscence was observed 16.5 v 8.6% P=0.044.[4]

Please note for greater than 15 years there has been wide usage of the NPWTi by the investigator. The evidence supporting the theoretical use of this device is beyond the scope of this protocol.

1.2 OBJECTIVE(S)

The primary objective is to assess the frequency of a wound healing complication, in a closed incisional wound in a "high risk" surgical incision when treated with NPWTi versus a highly absorbent antimicrobial post – operative absorbent dressing. (HAAMPOD).

> A healing complication is defined as presence of at least one of the following conditions: infection (superficial or deep), dehiscence (partial, superficial, or deep), or delayed healing (incision not 100% closed within 7 days of the first surgical procedure), drainage form the wound after 96 hours post operatively.

The secondary objectives are to assess any changes in the following assessments of the surgical incision weekly over the treatment period:

- Surrounding skin condition
- Incision complications, infection or clinical signs of infection
  - to assess the number and type of these complications individually including other postsurgical complications: skin necrosis, cellulitis, abscess, suture abscess, seroma, periwound edema or hematoma occurring within 21, 42, and 90 days postoperatively
- Pain during dressing changes

Assessment of the following at dressing changes:

- Duration/wear time
- Ease of use; difficulty with sleep
- Damage to surrounding skin on removal
- Assessment of re-epithelialization/closure
- Patient comfort during wear; ease of ambulation
- Conformability of dressing
- Exudate management
- Reasons for removal

To assess the overall comparison of Avance® Solo to the HAMMPOD.

2 EVALUATION DESIGN

2.1 EVALUATION DESIGN

Open label, two armed, prospective, single center, quality equivalency assessment.

Immediate post operative application of Avance® Solo Negative pressure wound therapy on "high risk" closed surgical incisions. Versus the hospital best clinical practice dressing HAAMPOD. (Please note there is no prospective clinical data driven data, the hospital purchasing department develops and indicates the brand based upon cost).

The patient will be undergoing:

- Foot and ankle surgery
- Vascular groin incision, vascular axillary incisions
- Long leg vein harvest incision
- Closed forefoot and major amputation surgery
- Possibly: breast augmentation and reduction surgery

*Note: The surgical indication is chosen based upon previously published data of high risk incisions. (It is beyond the scope of a protocol to educate the IRB in regards to the full definitions of high risk surgical inicisions)

Patients will participate in the study for 4 applications or up to 2 weeks treatment, whichever comes first. During this time clinicians will be asked to complete questions pertaining to the incision and to the performance and overall acceptability of Avance®Solo or the HAAMPOD.

Throughout the evaluation patients will be treated according to the product instructions for use for either product.

3 EVALUATION PRODUCT(S)

3.1 DESCRIPTION OF EVALUATION PRODUCT(S)

Avance® Solo will include the collective description for a complete device capable of delivering negative pressure to the incision site and managing exudate generated by the incision. It comprises:

“This investigation pertains to Avance®Solo, a single use battery powered negative pressure system, with Mölnlycke as the legal manufacturer with its headquarter located in Gothenburg, Sweden. Avance®Solo consists of different products that are FDA compliant, which together form a system for wound management via the application of negative pressure (Figure 2). Avance®Solo maintains negative pressure nominally at -125 mmHg on low and moderately exuding wounds. The pump is pocket sized and can be carried in a pocket or attached to a belt with a belt clip that is assembled with the pump. To maintain the pressure, there is a recycling sound. To reduce the sound of cycling, a night case can be used to facilitate comfort during sleep.”

A proprietary Controlled Fluid Management (CFM) technology, the Avance® Solo single use negative pressure system shares fluid management between an absorptive multi-layered dressing and a 50ml canister, reducing the potential for dressing saturation. This technology is theoretically designed to reduce the potential loss of therapy arising from dressing saturation.

- The addition of a canister to the absorptive dressing ensure the dressing does not become overwhelmed with draining and therapy will continue to be delivered regardless of dressing saturation

- Sharing fluid management between an absorptive dressing and canister can reduce the frequency of dressing changes
- Avance® Solo NPWT system continues to deliver negative pressure to the wound site, even with low to moderate amounts of fluid saturation in the dressing
- Avance® Solo features both audible and visual alarms so therapy can be restored in an efficient timely manner
- Avance Solo Border dressings Safetac® adhesive has been proven to minimise trauma to wound site and surrounding skin upon dressing removal
- -125mmHg continuous negative pressure

The pump is a controllable vacuum pump apparatus, which can be left to operate automatically, delivering continuous negative pressure (nominally -125mmHg) to the incision site. The pump's lifetime is 14 days and is powered with 2 lithium batteries specific to the pump. Batteries shall be replaced once pump alarms for Low battery or after 7 days.

The control product (HAAMPOD) has not undergone any prospective randomized controlled trial. (Optifoam® Gentle Post-Op). It has been deemed equivalent and acceptable therapy for the Mount Sinai West Operating room, by equivalency data by the Mount Sinai purchasing group.

Precautions:

The use of anticoagulants does not deem a patient inappropriate for treatment with the Avance® Solo, however, haemostasis must be achieved before applying the dressing and continued frequent assessment must be maintained and considered throughout the therapy.

Avance® Solo must not be placed over exposed arteries, veins or organs. Greater care should be taken with respect to weakened, irradiated or sutured blood vessels or organs.

Avance® Solo is contraindicated for patients with malignancy in the incision site or margins of the incision (except in palliative care to enhance quality of life), previously confirmed and untreated osteomyelitis, non-enteric and unexplored fistulaes, sinus tracts and areas of tunnelling or necrotic tissue with eschar or exposed anastomotic sites, use over exposed blood vessels, nerves or organs or use on exposed bone or tendon unless a non-adherent dressing is used to protect the exposed areas.

Avance® Solo is registered in the country of use (CE marked for Europe and 510k approved for the US).

A number of different dressing sizes are produced by the sponsor, Molnlycke (shown in Table 1).

Table 1: Molnlycke dressing sizes

Dressing size	Effective pad size	Pad Area (cm^2)

10cm x 20cm	5cm x 15cm	75
10cm x 30cm	5cm x 25cm	125
10cm x 35cm	5cm x 30cm	150
15cm x 15cm	10cm x 10cm	100
15cm x 20cm	10cm x 15cm	150
15cm x 30cm	10cm x 25cm	250
20cm x 20cm	15cm x 15cm	225
25cm x 25cm	20cm x 20cm	400

The dressing and pad sizes that will be used for the closed incision wounds in this study are listed below (shown in Table 2).

Table 2: Dressing sizes to be used in the study

Dressing size	Effective pad size	Pad Area (cm^2)
10cm x 20cm	5cm x 15cm	75
10cm x 30cm	5cm x 25cm	125
10cm x 35cm	5cm x 30cm	150
15cm x 20 cm	10cm x 15cm	150
15cm x 30cm	10cm x 25cm	250

3.2 **OPTIFOAM® GENTLE POST-OP – (MEDLINE IN, NORTHFIELD IL)** – IS A "SILICONE FACED AND BORDERED POST OPERATIVE FOAM AND SUPERABSORBENT CORE AND FLEXIBLE DESIGN." (PER PACKAGE INSERT) THIS PRODUCT IS DEEMED ADEQUATE FOR HIGH RISK SURGICAL INCISIONS PER MOUNT SINAI VALUE ANALYSIS/ (NOT SUBJECT TO IRB APPROVAL NOR REVIEW)/PURCHASING. WHICH WILL BE KEPT IN PLACE FOR UP TO 7 DAYS (PER PACKAGE INSERT), ALTHOUGH DRESSING CHANGES UP TO 4 PER 14 DAYS WILL BE ALLOWED. *NOTE THIS PRODUCT IS SUBJECT TO CHANGE BASED UPON MOUNT SINAI PURCHASING CONTRACTS.

Dressing size	Effective pad size	Pad Area (cm^2)
10.2 x 20.3 cm	5.1 cm x 15.2 cm	77.5
10.2 x 25.4 cm	5.1 cm x 20.3 cm	103.5
10.2 x 30.5 cm	5.1 cm x 25.4 cm	129.5

a. PACKAGING AND LABELLING

2. All evaluation products will be supplied in standard packaging. No additional labelling will be appended to the evaluation products.

5

a. METHOD OF DISTRIBUTION

3. Delivery of product and will be arranged and agreement between Molnlycke and the center.

3.3 RECONCILIATION

All evaluation products, which have not been used by the end of the evaluation, must be returned to Molnlycke. The clinician will maintain an inventory, which will include details of receipt, use and return of all evaluation products (Appendix 1). The control product will be managed by the Mount Sinai West operating room product acquisition supply system.

4 EVALUATION PATIENT POPULATION

4.1 NUMBER OF PATIENTS

30 patients in each arm meeting the inclusion criteria

4.2 PATIENT SOURCES

Patients will be recruited from the Mount Sinai West Hospital general (includes Plastic surgery as a Division of Plastic Surgery) and orthopedic surgery practices of foot and ankle surgery, vascular surgery, general surgery, and Plastic surgery. These practices have a similar location for outpatient follow-up of [redacted] New York New York, 10019. USA.

4.3 SELECTION CRITERIA

Patients with an incision deemed suitable for treatment with Avance® Solo or HAAMPOD will be screened against the inclusion and exclusion criteria. Only patients who meet the eligibility criteria will be included in the evaluation. For patients with more than one incision, only the largest or most suitable of their incisions will be included in the evaluation and will need to be in line with the instructions for use and contraindication instructions and will be an incision which fits the dressing sizes included.

Only 1 dressing per incision must be used on an incision and this incision will be referred to as the reference incision. Any other incisions the patient may have will be treated in accordance with standard local procedures. The 1st dressing will be placed immediately upon completion of the operation

4.3.1 Inclusion Criteria

The following criteria must be met before a patient is recruited to the evaluation:

- The patient must be at least 18 years of age
- Males and females - provided they are not pregnant and if of reproductive age are using contraception.
- Have a closed surgical incision post-surgery/closure (<24 hours after).
- The patient is able to understand the evaluation and is willing to consent to the evaluation.
- Undergoing appropriate: wound “high risk” surgery
- Foot and ankle surgery
- Vascular groin incision
- Long leg vein harvest incision
- Closed forefoot and major amputation surgery
- Breast augmentation and reduction surgery
- Patient on metabolic agent, immunosuppressants, or steroid therapy will not be excluded from this study
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4.3.2 Exclusion Criteria

- Incisions in excess of effective dressing pad size provided.
- Patients with a known history of poor compliance with medical treatment.
- Patients who have participated in this trial previously and who were withdrawn.
- Patients with known allergies to product components (silicone adhesives and polyurethane films (direct contact with incision), acrylic adhesives (direct contact with skin), polyethylene fabrics and super-absorbent powders (polyacrylates) (within the dressing).
- Incisions where daily inspection is required underneath the dressing.
- Incisions which have an infection which is not being treated with systemic antibiotics.
- Incisions which are actively bleeding.
- Exposure of blood vessels, organs, bone or tendon at the base of the reference incision.

4.3.3 Manufacturers recommended use will be adhered to:

- Before starting therapy, evaluate the patient’s nutritional status and address severe malnutrition.
- Signs of possible infection or complications must be addressed immediately. Monitor the device, wound, surrounding skin, and patient status accordingly to ensure effective and safe treatment and patient comfort.
- For patients with ischemic condition or at application of a circumferential dressing, extra monitoring of wound status is required to avoid risk of compromised circulation.

- Avance Solo Pump is equipped with visual and audible notifications and alarms. Ensure that carrying or placement of the pump allows the user to detect audible and visual notifications and alarms.
- When Avance Solo Pump battery low alarm is triggered, replace the batteries in the pump. Only use the type and model of lithium batteries specified for this product by Mölnlycke Health Care, see section 8.
- Fixation strips provided with the dressing shall only be applied on dressing borders. Do not apply fixation strips, or other occlusive dressings, across the dressing wound pad due to the risk of low breathability leading to maceration.
- Application of certain skin protection products or using cleansing products prior to the application of the dressing, can affect the ability of the dressing and fixation strips to adhere securely and create sufficient sealing.
- Do not use the products on patient and/or user with known hypersensitivity to the ingoing materials/components of the products.
- Ingrowth of tissue may occur if the dressing or wound filler is not changed in accordance with recommendations or as appropriate for the wound condition of the individual patient (See Section 6.6).
- Consider use of non-adherent wound contact layer (Mepitel) to protect fragile tissue.
- Do not place the pump with canister in water or other liquids. Disconnect the pump and canister if the ingress of water is observed.
- For daily hygiene routines do not expose the pump with canister or dressing to extensive contact with water.
- Avance Solo Border Dressing should only be applied and changed by healthcare professional.
- No modification of this device (pump, canister, tubing, dressing, foam) is allowed as modifications may significantly compromise the ability of the system to deliver therapy.
- Do not disassemble the pump.
- Products in Avance Solo NPWT System should not be used with products from other NPWT systems.
- Do not cut the tubing or detach tubing from the canister.
- Do not cut the dressing.
- For CT scans and X-ray investigations, keep the pump out of the X-ray or scanner range. In the event that the pump is within a CT-scan or X-ray range, ensure to check that the pump functions correctly after the procedure.
- Avance Solo Pump is not intended for use aboard aircraft. Remove batteries during air travel.
- Avance Solo NPWT System products are provided sterile. Do not use if the sterile barrier is damaged or has been opened prior to use. Do not re-sterilize.
- Avance Solo Pump is for single patient use.
- Avance Solo Border Dressing, Avance Solo Foam and Avance Solo Canister 50 ml are single use.
- Do not reuse Avance Solo NPWT System products. If reused, performance of the product may deteriorate, cross contamination may occur.
- HAAMPOD will be placed via commercially available dressing instructions.

Ensure that the battery lid on the Avance Solo Pump is closed during therapy.

4.4 WITHDRAWAL

Any patient who interrupts the evaluation treatment for longer than 3 days will be withdrawn from the evaluation.

Patients who do not respond to therapy should be withdrawn from the evaluation only at the point where it becomes necessary to change the treatment on clinical grounds.

Patients may drop out or be withdrawn for the following reasons:-

- at their own request*
- at the discretion of the clinician (because of lack of response, an adverse incident, poor compliance etc.).
- as their incision is no longer suitable for treatment with Avance® Solo

* Although patients need not give a reason for requesting withdrawal from the evaluation, the Clinician should make a reasonable effort to ascertain the reason(s), while fully respecting the patient's rights.

Patients who drop out or who are withdrawn from the evaluation will not be replaced if they have been entered onto the study and have received evaluation treatments.

Patients who drop out or who are withdrawn or whose wound heals will not be re-entered into the evaluation at a later date.

5 TREATMENT PLAN

5.1 TREATMENT REGIME

Patients will be informed of the evaluation requirements and asked to give informed consent prior to any evaluation activities taking place.

Patients meeting the eligibility criteria and agreeing to consent to their participation in this evaluation will receive treatment with Avance® Solo for a maximum of 2 kits or up to a maximum of 2 weeks treatment, whichever comes first. If randomized to HAAMPOD the patient will have a dressing applied per manufacturers guidelines. Up to 4 dressings will be applied over 14 days. Treatment will commence on Day 0 and dressing changes will take place as deemed necessary by the evaluation Clinician.

Avance® Solo should be applied in accordance with standard protocols and the product instructions for use.

The following table details the treatment regime for participation patients in the study.

Pre-Trial	Investigator discusses evaluation with the patient and provides the patient with a centre consent form

		for use of their data and photographs. Patient provides informed consent Complete eligibility checklist and medical history
Maximum of 2 weeks Treatment	First Dressing Application (Day 0)	Incision assessment Incision photograph First dressing application Video recording may be carried out
	Second Dressing Application	First dressing removal Incision assessment Incision photograph Second dressing application Video recording may be carried out
	Third Dressing Application	Second dressing removal Incision assessment Incision photograph Third dressing application Video recording may be carried out
	Fourth Dressing Application	Third dressing removal Incision assessment Incision photograph Fourth dressing application Video recording may be carried out
	Post Study	A patient interview may be carried out

At each dressing change the following will be assessed:

- Duration/wear time
- Ease of use;
- Difficulty with sleep
- Damage to surrounding skin on removal
- Assessment of re-epithelialization/closure
- Patient comfort during wear
- Ease of ambulation
- Conformability of dressing
- Exudate management
- Reasons for removal

5.2 FURTHER POST OPERATIVE EVALUATION

The patient will be seen on day 21 (±3), 42 (± 5) and 90 (± 7) at all time points the wounds will be assessed for:

Healing complications, defined as presence of at least one of the following:

- infection (superficial or deep)
- dehiscence (partial, superficial, or deep)
- delayed healing (incision not 100% closed within 7 days of the first surgical procedure).
- Ongoing wound drainage > 7 days post operatively

Secondary objectives are to assess the number and type of these complications individually including:

- wound drainage, type and amount;
- wound margin and periwound areas;
- and other aspects including but not limited to odor, pain, and need for debridement.
- skin necrosis, incisional pain, cellulitis, abscess, suture abscess, or hematoma occurring within 21, 42, and 90 days postoperatively.

5.3 RESTRICTIONS

In the event that defibrillation is required, disconnect the pump from the dressing prior to defibrillation. Remove the dressing if it is positioned in a location that will interfere with defibrillation.

Avance® Solo is not MRI compatible. Do not take Avance Solo into the MRI suite.

Avance® Solo has not been studied on paediatric patients. Patient size and weight should be considered when prescribing this therapy.

Avance® Solo is unsuitable for use in areas where there is a danger of explosion (e.g. hyperbaric oxygen unit).

Avance® Solo is not suitable for use in the presence of a flammable anaesthetic mixture or with oxygen or nitrous oxide.

The use of anticoagulants does not deem a patient inappropriate for treatment with **Avance® Solo** , however haemostasis must be achieved before applying the dressing and continued frequent assessment must be maintained and considered throughout the therapy.

At all times care should be taken to ensure that the pump and tubing does not:

- Lie in a position where it could cause pressure damage to the patient.
- Trail across the floor where it could present a trip hazard or become contaminated.
- Present a risk of strangulation or a tourniquet to patients.
- Rest on or pass over a source of heat.
- Become twisted or trapped under clothing or bandages so that the negative pressure is blocked.

6 EVALUATION METHODOLOGY

6.1 ASSESSMENT TIME-POINTS AND DATA RECORDED

Patients will have 2 Avance® Solo kits available (each with 2 dressings) and data will be captured on all dressing changes conducted with these 2 kits. No additional procedures will be carried out, outside of the patient's standard treatment. (for batteries are provided with each pump, additional battery should not be required). For the control arm up to 4 products per 14 day period will be provided.

At baseline assessment the following parameters will be requested prior to application of dressings:

- Treatment setting (Operating room/hospital bed)
- Dressing routinely used (Foam, Film, non-woven, hydrocolloid, alginate, other)
- Patient demographics (Age, gender)
- Size of dressing used Type of surgery Date of surgery
- Location of surgical incision site (Left or right side, head/neck, chest, back, abdomen, retroperitoneal, groin, upper or lower arm, upper or lower leg, other)
- Risk factors for a surgical incision healing complication (obesity, smoker, low vascularity, diabetes, radiotherapy, immuno-compromised patient, or other)
- Length of incision (cm)
- Method of closure (Sutures, staples, tissue adhesive/glues, skin closure tape, other)
- Exudate level (None, slight, moderate, heavy)
- Drain present (yes/no)
- Condition of surrounding skin (Healthy, inflamed, macerated, dry and flaky, other)
- Assessment of infection (yes/no)
- Any incision complications and / or clinical signs of infection present (None, incision site static or deteriorating, dehiscence, increased exudate/secretion levels, increased pain, increased temperature around the wound, discolouration of granulation tissue, friable granulation, tissue necrosis, local erythema, oedema, purulent drainage, odour, other)

Photographs (yes/no)

At all dressing change assessments the following information will be requested

- Conformability of dressing (yes/no)
- Treatment setting (Operating room, hospital bed, clinic, home, other)
- Size of dressing used
- Photographs (yes/no)
- Pain on application of dressing (None, mild, moderate, severe)
- Ease of use at this assessment

At dressing removals the following information will be requested

- Dressing changed since last assessment (yes/no) (if yes how many times has the dressing been changed).
- Dressing in place (yes/no) – obtain photograph
- Damage to surrounding skin (none, mild, moderate, severe)
- Level of damage to the reference wound on removal (none, slight, moderate, severe)
- Level of damage to the surrounding skin on removal (none, slight, moderate, severe)
- Condition of surrounding skin on removal (Healthy, fragile, inflamed, macerated, dry and flaky, other)
- Assess closure/ re epithelialisation of the incision
- Patient comfort during wear (Very comfortable, comfortable, acceptable, uncomfortable, very uncomfortable)
- Exudate level (None, slight, moderate, heavy)
- Assessment of infection (yes/no)
- Any incision complications and / or clinical signs of infection present (None, incision site static or deteriorating, dehiscence, increased exudate/secretion levels, increased pain, increased temperature around the wound, discolouration of granulation tissue, friable granulation, tissue necrosis, local erythema, oedema, purulent drainage, odour, other)
- Photographs (yes/no)
- Pain on removal of dressing (None, mild, moderate, severe)
- Reasons for removal (Dressing saturated, strike through, leakage, pain, Fell off, removed by patient, suture/staple removal, patients own request, inspection prior to patient discharge, other)
- Ease of use at this assessment (only at final removal)
- Occurrence of any product related adverse events will be documented at any point during the evaluation if required
- Is another dressing being applied at this assessment (yes / no?)

<u>At end of evaluation</u>

- Reason for discontinuation (end of evaluation, wound closed, treatment interrupted for more than 3 days, Wound progressed sufficiently to warrant a change in treatment, patient withdrawn)
- Reason for patient withdrawal (product related adverse event, lack of response, poor compliance, patients own request, other)
- Overall acceptability of Avance®Solo to clinicians for indicated use (yes/no)
- Whether the clinicians were sufficiently satisfied with the following properties of the product overall in terms of:

- Exudate management
- Conformability
- Number of dressing changes, strips, pumps, canisters and batteries used
- Barrier to infection
- Condition of surrounding skin
- General (Ease of use, Dressing retention, durability, patient comfort & convenience)

- Pain on application of dressing (0-10 SCALE)
- Pain on removal of dressing (0-10 SCALE)
- Overall performance of dressing (1-5)
- Freedom from re-admission
- The use of post operative antibiotics
- The duration of post operative antibiotics if used

Comparison of Avance®Solo with HAAMPOD, whether the clinicians were satisfied with Avance®Solo compared to HAAMPOD:

- Exudate management
- Conformability
- Number of dressing changes
- Barrier to infection
- Condition of surrounding skin
- General (Ease of use, Dressing retention, durability, patient comfort & convenience)
- Pain on application of dressing
- Pain on removal of dressing
- Overall performance of dressing
- Use of post operative oral antibiotics

6.2 PHOTOGRAPHS

- Photographs will be taken with de-indentified periwound stickers; the patient number, date, dressing change number and protocol reference number should be entered. The label should be placed so that it lies flat along one of the borders of the incision site and not covering any part of the incision.
- When taking photographs ensure that the label details and wound are clearly visible and that the wound takes up the majority of the photograph area.

7 ADVERSE EVENTS

This evaluation is being conducted on a product which is available commercially and which is being used within its licensed indications, according to its instructed method of use. In addition, the patient is being treated according to normal practice and no invasive or non-routine assessments are being taken. Therefore, only adverse events that are related to the evaluation product are to be reported.

Adverse Event Reporting. Throughout the Study, Sponsor Investigator agrees to procure that any Device Deficiency ("**DD**"), Adverse Device Effect ("**ADE**") and Serious Adverse Device Effect ("**SADE**") (all as further described in Exhibit A) that are considered as being related to the use of the medical device Avance Solo is reported in accordance with applicable local and/or regulatory requirements and, in addition thereto, be communicated in connection to the regular reports as described in clause **Error! Reference source not found.**. Institution shall ensure that it and the

Sponsor-Investigator respond promptly to all requests for follow-up information from Molnlycke. Institution shall ensure that it and Sponsor-Investigator inform IRB of any adverse event, in accordance with the policies and procedures of IRB."

A product related adverse event is any untoward medical occurrence which was possibly, probably or highly probably caused by the use of the evaluation product. If a product related adverse event occurs the evaluation clinician should complete the Clinical Evaluation Adverse Event Form and fax it to the Mölnlycke.

8 STATISTICAL CONSIDERATIONS

A Chi squared evaluation of the data will be carried out in regard to the dichotomous yes/ no variable of post operative wound complication of not. The two groups will be randomized based upon a computer generated randomization schedule. Due to the small numbers the randomization will not be controlled for the surgical type.

Based upon the current literature the expected wound complication rate of the associated wound complication rate would be 16% (or 5/30), based upon best treatment effect of NPWTi the rate of wound complication would be 8% or (2/30). While this is a clinically significant and cost significant difference, in order to show a statistically significant difference at these levels, with an Pβ of 0.8 and a Pα of 0.05, the study would have to enroll a cohort of 324 patient with 162 patients in each. To date no study of post operative wound dressings has approached this level of statistical validity. Prior to embarking on any such study, a pilot study such as this needs to be undertaken to validate the basic assumptions.

Cost analysis of post operative wound complications will not be collected as a portion of this data, although LOS and freedom from readmission will be assessed. The data set is seen as exploratory and is not powered to find statistical significance.

9 ADDITIONAL INFORMATION

9.1 RECORD KEEPING

9.1.1 Questionnaires

The questionnaires provided created by the investigator team, and will be used to document all findings related to the evaluation. Please complete all questions legibly in ink. Where possible please write any text in English.

9.1.2 Evaluation File

The evaluation file provided by the information technology services at Mount Sinai healthcare system, it is a fire wall protected HIPPA. Evaluation files will not be kept on personal computers, thumb drives and will only be used on hospital based IT supported systems.

9.2 EVALUATION PROGRESS UPDATES

This sponsor can ask for appropriate progress updates during the course of the evaluation

9.3 USE OF EVALUATION FINDINGS

The investigator will not use the results of this evaluation without the written consent of the Mölnlycke, for the purposes of this document e-mail communication is equivalent to written consent.

The goal of the evaluation will be a minimum of an abstract submission at a mutually agreed upon national and/or international meeting.

Secondary goal of the evaluation will be to provide a nidus for publication in and national or international journal.

10 ETHICAL AND LEGAL ISSUES

10.1 DECLARATION OF HELSINKI

The evaluation will be performed in accordance with the guidelines of the Declaration of Helsinki (1964) and subsequent revisions. A copy of the current Declaration of Helsinki will be provided if requested by the evaluation Clinician.

10.2 CONFIDENTIALITY

The patient will be identified throughout the evaluation and documentation by the number allocated to them during the evaluation. The sponsor will therefore not receive any information that could be used to identify patients participating in the evaluation.

10.3 INSURANCE

Product Liability Insurance has been purchased by Mölnlycke.

10.4 PATIENT CONSENT

Patients will be screened by the PI, study investigators, and coordinators through a medical record review in order to identify potentially eligible patients. Study personnel conducting a medical record review for potential subjects will look for elements of PHI that will help research personnel determine eligibility (based on the inclusion and exclusion criteria listed earlier) and enable them to inform study physicians of eligible participants. These identifiers include the following: Names, all geographic subdivisions smaller than a state, all elements of dates (except year) for

dates directly related to an individual, telephone numbers, social security numbers, medical records numbers, photographic images and videos of the study wound (these images will not contain identifiers). Only these identifiers will be shared with the study physicians via email from research personnel to determine if it is appropriate to approach the patient about the study. These candidates will be identified by study investigators.

Before being admitted to the clinical evaluation, the patient must have consented to the collection of their data during their participation in the evaluation, after the nature, scope and possible consequences of the evaluation have been explained in an understandable form. Candidates will be consented in a private setting and their information will be kept confidential, as only de-identified information will be collected from their for the purpose of the study. Subjects will consent to the indefinite retention of their de-identified data.

Although a specific consent form is not being provided for this evaluation, the questionnaires contain a space for the evaluation Clinician to sign to confirm that they have explained the evaluation to the patient and that the patient has agreed to take part.

For markets or centres where ethics or IRB approval is not required consent will still be required. Where ethics or IRB is required an approved consent form will be used.

The Clinician will not undertake any measures relating to the evaluation until consent has been obtained.

After consent is obtained, data will be collected from the EMR, study specific procedures, and the patient to complete screening, follow-up and final visit documentation, as well as the patient satisfaction questionnaire.

References

1. Horch RE. Incisional negative pressure wound therapy for high-risk wounds. J Wound Care. 2015 Apr;24(4 Suppl):21-8. doi: 10.12968/jowc.2015.24.Sup4b.21. PMID: 25853645.

2. Brandon T. A portable, disposable system for negative-pressure wound therapy. Br J Nurs. 2015 Jan 22-Feb 11;24(2):98, 100-6. doi: 10.12968/bjon.2015.24.2.98. PMID: 25615995.

3. Pachowsky, M., Gusinde, J., Klein, A., Lehrl, S., Schulz-Drost, S., Schlechtweg, P., Pauser, J., et al. (2011). Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty. International orthopaedics. doi:10.1007/s00264-011-1321-8

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