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Veraflo™

Start smart with Solventum™ Veraflo™ Therapy

Important information

- It is important for providers to consult the treating physician and read and understand all device Instructions for Use, including Safety Information
- Solventum recommends clinicians participate in device in-service and training prior to use
- Follow local institutional protocols for infection control and waste disposal procedures. Local protocols should be based on the applicable federal, state and/or local government environmental regulations
- The following slides include case studies and/or clinical reports based on clinical experience and research. As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition
- Scientific research was conducted by Solventum employees and consultants

Note: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only

Solventum™ Veraflo™ Therapy with Solventum™ V.A.C.® Ulta™ Therapy Unit indications for use

An integrated wound-management system that provides NPWT with an instillation option.

Indications for: Veraflo Therapy

Veraflo Therapy, consists of negative pressure wound therapy (Solventum™ V.A.C.® Therapy) coupled with controlled delivery and drainage of topical wound treatment solutions and suspensions over the wound bed (Instillation Therapy).

- V.A.C.® Therapy is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material
- Instillation Therapy is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed. When used with Solventum™ Veraflo Cleanse Choice™ Dressing or 3M™ Veraflo™ Cleanse Choice Complete™ Dressing, it provides hydromechanical removal of infectious materials, non-viable tissue and wound debris which reduces the number of surgical debridements required, while promoting granulation tissue formation, creating an environment that promotes wound healing*

The 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit and Solventum™ Veraflo Cleanse Choice™ Dressing Kit is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts.

Wound types: The V.A.C.® Ulta Negative Pressure Wound Therapy System with instillation is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure, and venous insufficiency), flaps and grafts.

*K221585

Solventum™ V.A.C.® Ulta™ Therapy Unit contraindications

Do not place foam dressings of the V.A.C.® Ulta Therapy System (including Solventum™ Veraflo™ Therapy) directly in contact with sensitive structures such as exposed blood vessels, anastomotic sites, organs, or nerves.

Note: Refer to the Warnings section [of device labeling] for additional information concerning bleeding.

Veraflo Therapy and 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit are contraindicated for patients with:

- Malignancy in the wound
- Untreated osteomyelitis

Note: Refer to the Warnings section of IFU for osteomyelitis information.

- Non-enteric and unexplored fistulas
- Necrotic tissue with eschar present*

Note: After debridement of necrotic tissue and complete removal of eschar, Veraflo Therapy may be used.*

Veraflo Therapy specific contraindications:

- Do not use Solventum™ Veraflo™ Dressings with Octenisept® (Schülke & Mayr GmbH), hydrogen peroxide or solutions that are alcohol-based or contain alcohol
- Do not deliver fluids to the thoracic cavity or abdominal cavity due to the potential risk to alter core body temperature and the potential for fluid retention within the thoracic cavity
- Do not use Veraflo Therapy unless the wound has been thoroughly explored due to the potential for inadvertent instillation of topical wound solutions to adjacent body cavities

*Does not apply to Solventum™ Veraflo Cleanse Choice™ Dressing or Veraflo Cleanse Choice Complete Dressing.

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3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit

Indications for use

The Veraflo Cleanse Choice Complete Dressing Kit is used as part of an integrated wound therapy system that provides Solventum™ Veraflo™ Therapy which consistent of negative pressure wound therapy (Solventum™ V.A.C.® Therapy) with an instillation option. It is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts.

The instillation option is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed. It provides hydromechanical removal of infectious materials, non-viable tissue and wound debris which reduces the number of surgical debridements required, while promoting granulation tissue formation, creating an environment that promotes wound healing.

3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit

Contraindications

- Do not place the 3M™ Veraflo™ Cleanse Choice Complete™ Dressing directly in contact with exposed blood vessels, anastomotic sites, organs or nerves

Note: Refer to the Warning section of the Indication for Use for additional information concerning bleeding

- Solventum™ Veraflo™ Therapy is contraindicated for patients with:
  - Malignancy in the wound
  - Untreated osteomyelitis

Note: Refer to Warnings section for Osteomyelitis information.

- Non-enteric and unexplored fistulas
- Do not use Veraflo Cleanse Choice Complete Dressing with Octenisept®, hydrogen peroxide or solutions that are alcohol-based or contain alcohol
- Do not deliver fluids to the thoracic or abdominal cavity due to the potential risk to alter core body temperature and the potential for fluid retention within the cavity
- Do not use Veraflo Therapy unless the wound has been thoroughly explored due to the potential for inadvertent instillation of topical wound solutions to adjacent body cavities

Solventum™ Veraflo™ Therapy: Your strategic Plan A instead of a Plan B when other therapies fail

Goals for using Veraflo Therapy are varied and include:[1,2]

Granulation tissue formation

- Increase granulation formation
- Decrease wound volume

Wound cleansing

- Remove infectious materials
- Helps manage bioburden through repeated cleansing and NPWT cycles[3]
- Decrease viscosity and volume of exudate
- Remove non-viable tissue and wound debris with 3M™ Veraflo™ Cleanse Choice Complete™ Dressing or Solventum™ Veraflo Cleanse Choice™ Dressing

References: 1. Kim PJ, Attinger CE, Crist BD, et al. Negative pressure wound therapy with instillation: review of evidence and recommendations. *Wounds*. 2015;27(12):S1-S20. **2.** Gupta S, Gabriel A, Lantis J, Teot L. Clinical recommendations and practical guide for negative pressure wound therapy with instillation. *Int Wound J*. 2016;13:159-17. **3.** Kim PJ, Lavery LA, Galiano RD, et al. The impact of negative-pressure wound therapy with instillation on wounds requiring operative debridement: Pilot randomised, controlled trial. *Int Wound J*. 2020;115. https://doi.org/10.1111/iwj.13424

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Clinical case summary: Solventum™ Veraflo™ Dressing on a clean wound

Goal: Granulate of the wound from removal of large basal cell carcinoma

A 73-year-old male presented to a long-term acute care (LTAC) facility with a large left posterior basal cell carcinoma lesion and subsequent radical surgical resection. At the time of LTAC admission, the deficit measured 26 cm x 27 cm x 1.2 cm. A primary wound contact layer of non adhering silicone dressing was first applied to protect exposed structures. Veraflo Therapy was initiated, and dressing changes were performed three times a week with 25–35 mL of normal saline was instilled with a 20-minute dwell time, followed by 2 hours of continuous negative pressure at −125 mmHg. By Week 2, the wound improved with increased granulation tissue, contracting wound edges, and new epithelial tissue formation. After 3 weeks of treatment, Veraflo Therapy was discontinued and the patient was discharged with 3M™ Promogran Prisma™ Matrix was applied to the wound. When the patient was home, Solventum™ ActiV.A.C.™ Therapy System was initiated with continuous negative pressure at -150 mmHg. Five weeks after starting negative pressure wound therapy, the patient was prepared for skin graft closure. Split tissue skin grafts taken from the anterolateral thigh were placed over the wound and bolstered with continuous negative pressure at -125 mmHg 3M™ Promogran Prisma™ Collagen Matrix with ORC and Silver was used on the donor site that healed without incident by postoperative day 6.

Instillation solution: Saline

Dwell time: 20 minutes

NPWT time: 2 hours

Pressure setting: 125 mmHg

Dressing changes: 48-72 hours

Day 0: Application of non-adhering silicone dressing to protect exposed structures followed by Solventum™ Veraflo™ Therapy.

Day 7: Veraflo Therapy; granulation tissue formation.

Day 21: Veraflo Therapy discontinued.

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Reference: Patient data and photos courtesy of Brian Bradow, MD, Peoria, IL

Clinical case summary: Solventum™ Veraflo Cleanse Choice™ Dressing on a dirty wound with deficit

Goal: Clean and granulate hematoma debridement

A 73-year-old male patient with leg wound post hematoma debridement. Comorbidities included atrial fibrillation, chronic obstructive pulmonary disease, peripheral vascular disease (PVD), hyperlipidemia, morbid obesity, coronary artery disease and congestive heart failure. Patient was treated with systemic antibiotics. Solventum™ Veraflo™ Therapy was initiated with Veraflo Cleanse Choice Dressing.

Instillation solution: Saline

Dwell time: 5 minutes

NPWT time: 2 hours

Pressure setting: 125 mmHg

Dressing changes: 48-72 hours

Day 0: One week following debridement of right leg wound. Veraflo Therapy with Veraflo Cleanse Choice Dressing was applied.

Day 6: Wound after 2 dressing changes. Significant reduction in non-viable tissue and rapid increase in granulation tissue formation noted.

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Reference: Patient data and photos courtesy of Garrett A. Wirth, MD, MS, FACS

Clinical case summary: Solventum™ Veraflo Cleanse Choice™ Dressing on a dirty wound with stalled healing

Goal: Clean and granulate venous leg ulcer

A 60-year-old female with a venous leg ulcer. Comorbidities included peripheral vascular disease, obesity, hypertension, thyroid disease, gastroesophageal reflux disease, respiratory failure, influenza A infection, an infected right leg wound with cellulitis, and septic shock. Systemic antibiotics were initiated upon presentation. Tubular compression was utilized to assist with edema management.

Instillation solution: ¼ strength

Dakin's solution; After 24 hours, normal saline was used.

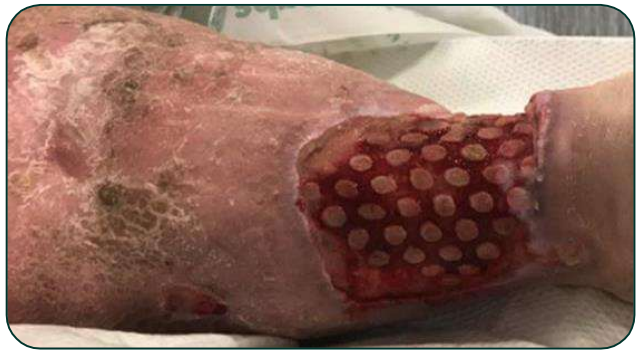
Dwell time: 10 minutes

NPWT time: 1 hour

Pressure setting: -125 mmHg

Dressing changes: 48-72 hours

Day 0: Application of Solventum™ Veraflo™ Therapy with Veraflo Cleanse Choice Dressing.



Day 1: Wound at first dressing change after 24 hours. Significant reduction in non-viable tissue and rapid increase in granulation tissue formation noted.

Reference: Patient data and photos courtesy of Kersten Reider, BSN, RN, CWOCN and Elizabeth Faust, MSN, RN, CRNP, CWS, CWOCN-AP, Tower Health System, West Reading, PA

Solventum™ Veraflo™ Therapy

Overview

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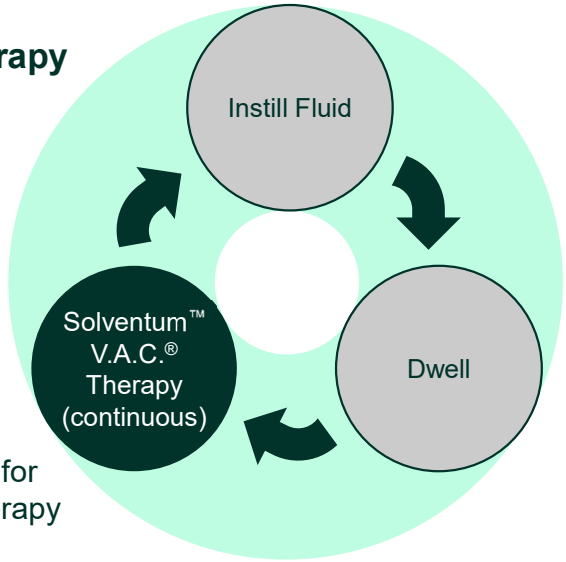
Solventum™ Veraflo™ Therapy

Veraflo Therapy combines the benefits NPWT with an instillation therapy option featuring both **automated volumetric delivery** of topical wound treatment solutions with a **programmable soak feature** which allows solution to dwell in the wound for thorough contact.

Veraflo Therapy (NPWTi-d)



Cycle repeats for duration of therapy

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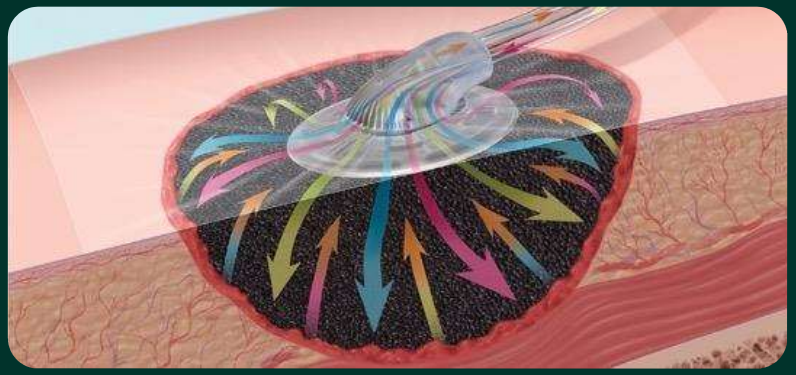
Veraflo Therapy can help

Cleanse the wound with instillation of topical wound cleansers in a consistent, controlled manner.

Treat the wound with the instillation of appropriate topical antimicrobial and antiseptic solutions and the removal of infectious material.

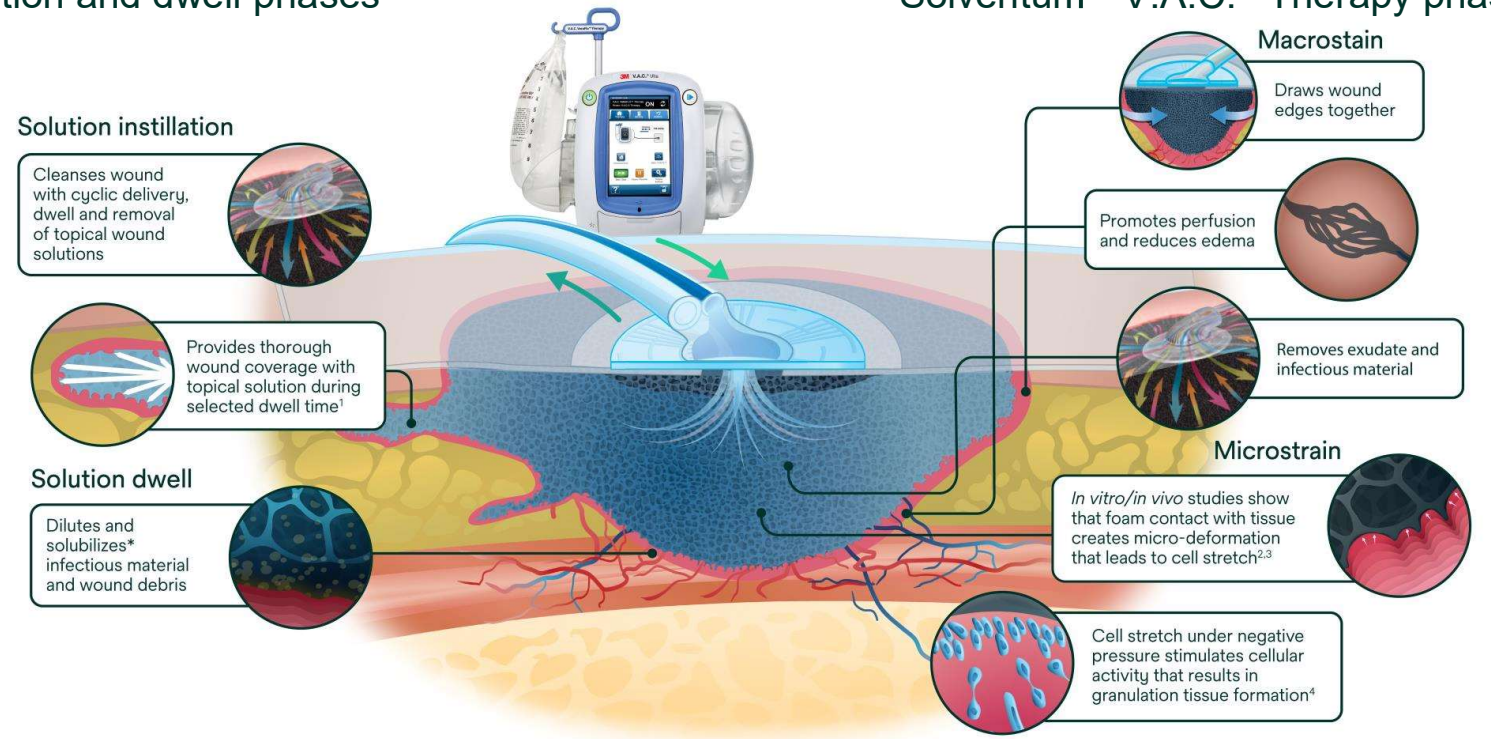
Prepare for delayed primary or secondary closure.



Solventum™ Veraflo™ Therapy mechanisms of action (MOA)

Instillation and dwell phases

Solventum™ V.A.C.® Therapy phase



*Topical solution dependent

References: 1. Rycerz AM, Slack P, McNulty AK. Distribution assessment comparing continuous and periodic wound instillation in conjunction with negative pressure wound therapy using an agar--based model. Int Wound J. 2013;10:214--20. DOI: 10.1111/j.1742--481X.2012.00968.x. **2.** Saxena SM, et al. Vacuum Assisted Closure: Microdeformations of Wounds and Cell Proliferation. Plastic & Reconstructive Surgery. 2004; 114(5):1086--1095 **3.** McNulty AK, et al. Effects of negative pressure wound therapy on cellular energetic in fibroblasts grown in a provisional wound (fibrin) matrix. Wound Repair and Regeneration. 2009 Mar;17(3):192--9 **4.** McNulty AK, et al. Effects of negative pressure wound therapy on the fibroblast viability, chemotactic signaling and proliferation in a provisional wound (fibrin) matrix. WOUNDS. 2007; 15:838--846.

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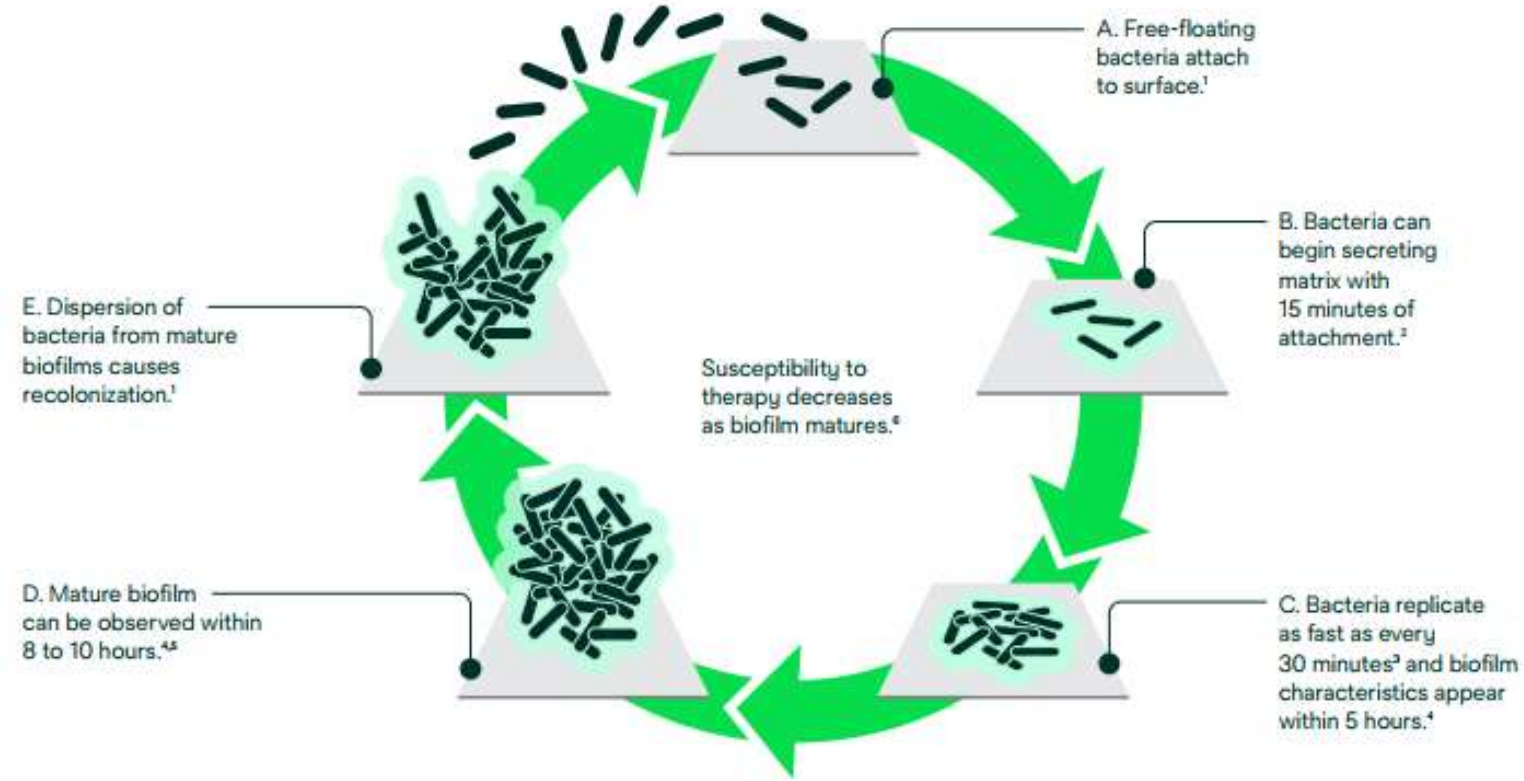
Bioburden lifecycle



References: 1. Costerton JW, Stewart PS, Greenberg EP. Bacterial biofilms: a common cause of persistent infection. Science. 1999; 284 (5418):1318-1322. **2.** Davies DG, Geesey GG. Regulation of the alginate biosynthesis gene algC in pseudomonas aeruginosa during biofilm development in continuous culture. Appl Environ Microbiol. 1995; 61(3):860-867. **3.** Cicmanec F, Holder IA. Growth of pseudomonas aeruginosa in normal and burned skin extract: role of extracellular proteases. Infect Immun. 1979; 25(2): 477-483. **4.** Harrison-Balestra C, Cazzaniga BS, Davis SC, et al. A wound-isolated pseudomonas aeruginosa grows a biofilm in vitro within 10 hours and is visualized by light microscopy. Dermatol Surg. 2003: 29(6):631-635. **5.** Schaber JA, Triffo WJ, Suh SJ, et al. Pseudomonas aeruginosa forms biofilms in acute infection independent of cell-to-cell signaling. Infect Immun. 2007; 75(8):3715-3721. **6.** Wolcott RD, Rumbaugh KP, James G, et al. Biofilm maturity studies indicate sharp debridement opens a time-dependent therapeutic window. J Wound Care. 2010; 19(8):320-328.

Infected wounds prevalence[1]

Survey data showed 35% of customers do not treat infected wounds with NPWT

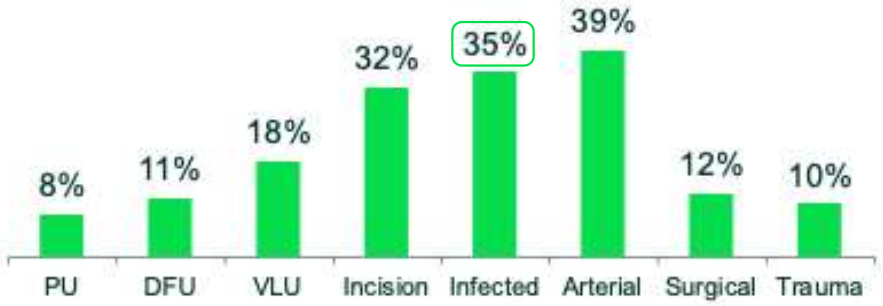
Question: Can you categorize the percentage of wounds you treat upon initial evaluation?

- 33% – Clean (Non-Replicating Microbes, Healing not inhibited)
- 27% – Contaminated (Replicating Microbes, Body can defend)
- 21% – Critically Colonized (Overgrowing Microbes, Delayed Healing)
- 19% – Infected (Invasion, Systemic Reaction, Healing Impaired)

Note: NPWT is not cleared to treat infection.

Survey data showed 35% of customers do not use NPWT in wounds with infection

Question: Which wound types would you not use NPWT on?



References: 1. September 2014 Survey, n=240, Surgeons, Podiatrists, WOCNs and PTs.

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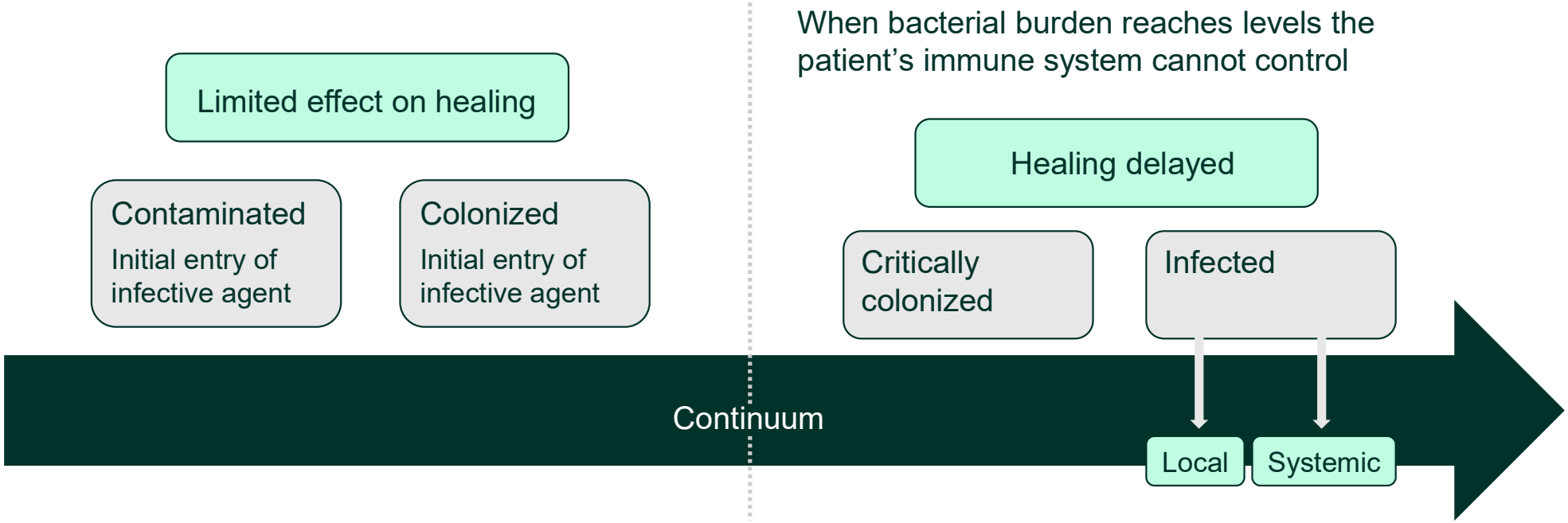
Bacterial burden continuum[1]



Note: Solventum™ Veraflo™ Therapy is not indicated for treatment of infection, for the prevention or treatment of biofilm, or for the delivery of non-topical antibiotics or drugs.

References: 1. Kingsley A. The wound infection continuum and its application to clinical practice. Ostomy Wound Manage 2003;49:1-7.

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Solventum™ Veraflo™ Therapy

Evidence

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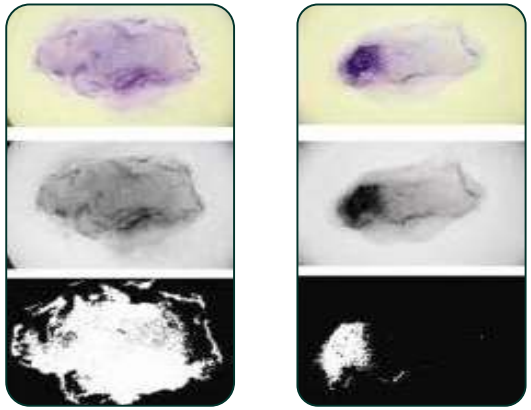
Bench study: Instillation solution distribution[1]

Solventum™ Veraflo™ Therapy vs NPWT with continuous irrigation

Benchtop Agar-Based anatomical wound model

Veraflo Therapy*

NPWT w/continuous irrigation**

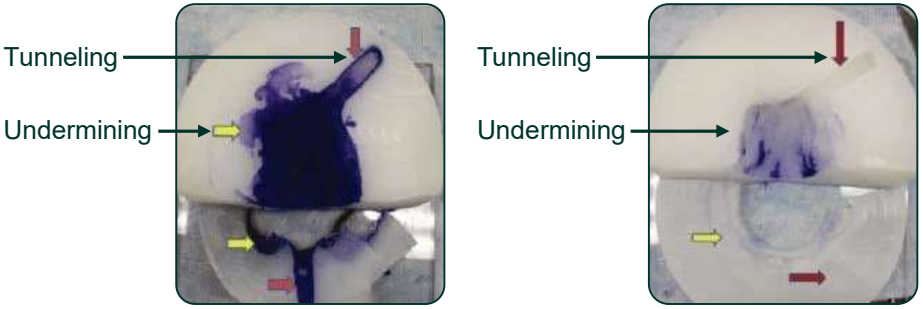


NPWT with continuous irrigation did not provide even coverage.

Complex geometry wound models

Veraflo Therapy

NPWT w/continuous irrigation



Veraflo Therapy provided uniform coverage of wound with irrigation solution and reached tunneled and undermined regions.

*Periodic instillation (NPWTi): 3 cycles of 10-minute dwell time followed by continuous -125 mmHg.
**Continuous irrigation: 30 cc/hr streaming for 3.5 hours with continuous -125 mmHg.

Reference: 1. Rycerz A, Slack P, McNulty A. Distribution assessment comparing continuous and periodic wound instillation in conjunction with negative pressure wound therapy using an agar-based model. Int Wound J. 2013 Apr;10(2):214-20.

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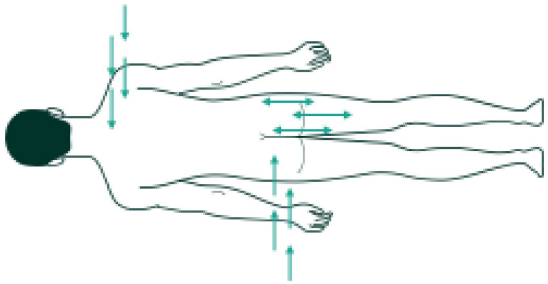
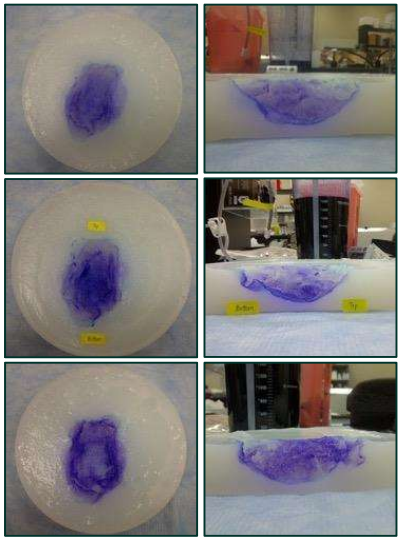
Bench study: Instillation solution distribution multiple orientatons[1]

Wound location/orientation

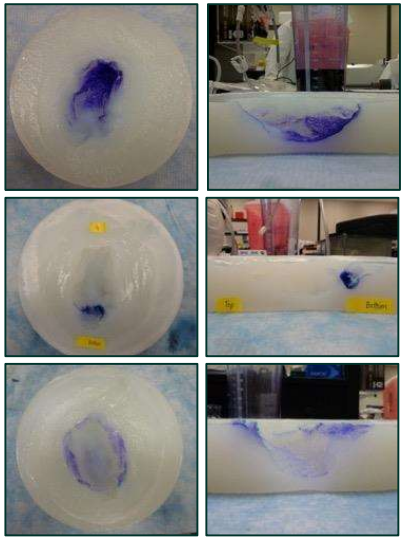


Direction of fluid delivery

Solventum™ Veraflo™ Therapy



NPWT w/continuous irrigation



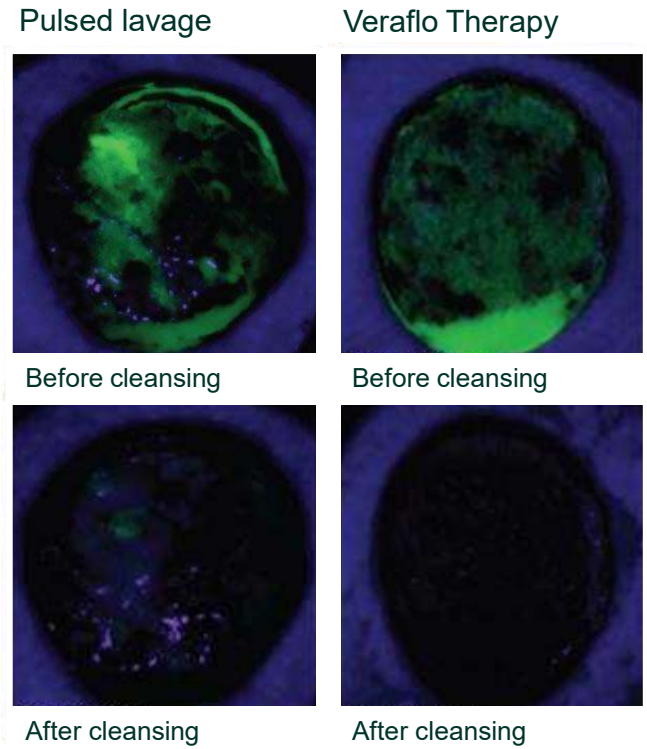
NPWTi-d (periodic instillation/dwell time) provided uniform coverage of the wound bed, independent of orientation.

Reference: 1. Rycerz A, Slack P, McNulty A. Distribution assessment comparing continuous and periodic wound instillation in conjunction with negative pressure wound therapy using an agar-based model. Int Wound J. 2013 Apr;10(2):214-20.

Cleaning the wound bed: Solventum™ Veraflo™ Therapy vs. pulsed lavage[1]

Porcine study: Wound cleansing and tissue damage

- Contralateral porcine wounds were inoculated with fluorescein-dextran and cleansed with saline
  - **Pulsed lavage pressure:** 4 to 15 PSI
  - **Veraflo Therapy pressure:** less than 3 PSI
- Cleansing was evaluated with a fluorescence camera system before and after cleansing
- Swelling was measured with a 3D camera system



Reference: 1. Allen D, LaBarbera L, Bondre I, et al. Comparison of tissue damage, cleansing and cross-contamination potential during wound cleansing via two methods: lavage and negative pressure wound therapy with instillation. Int Wound J. 2012 Aug;11(2):198-209.

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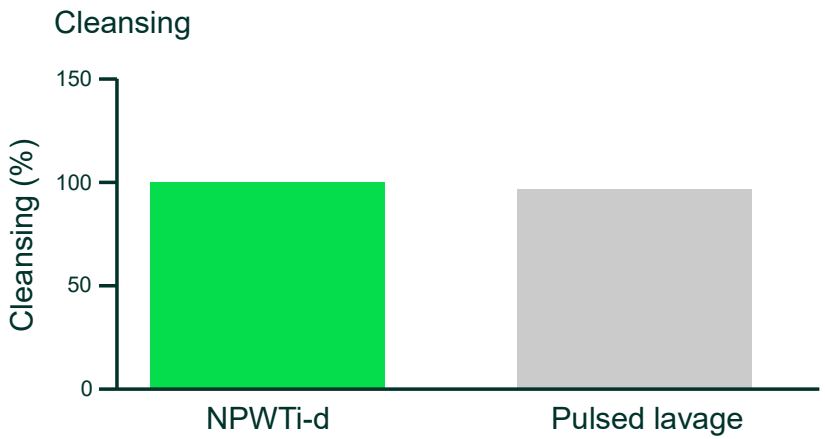
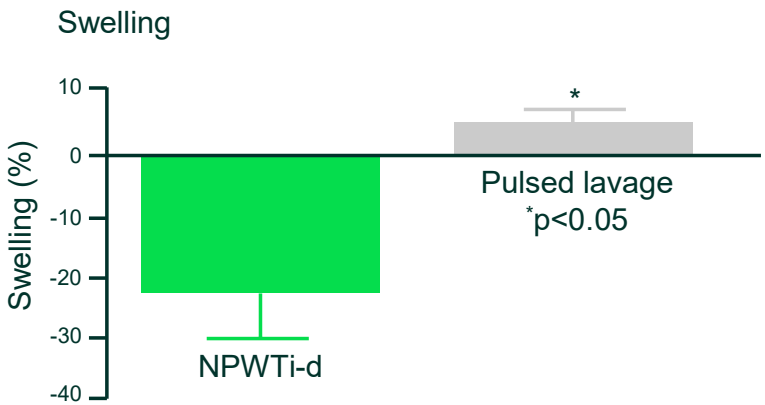
Cleaning the wound bed: Solventum™ Veraflo™ Therapy vs. pulsed lavage

Porcine study: Wound cleansing and tissue damage[1]





- Pulsed lavage was shown to cleanse wounds, but caused swelling
- Veraflo Therapy equivalently cleansed wounds without causing swelling

Reference: 1. Allen D, LaBarbera L, Bondre I, et al. Comparison of tissue damage, cleansing and cross-contamination potential during wound cleansing via two methods: lavage and negative pressure wound therapy with instillation. Int Wound J. 2012 Aug;11(2):198-209.

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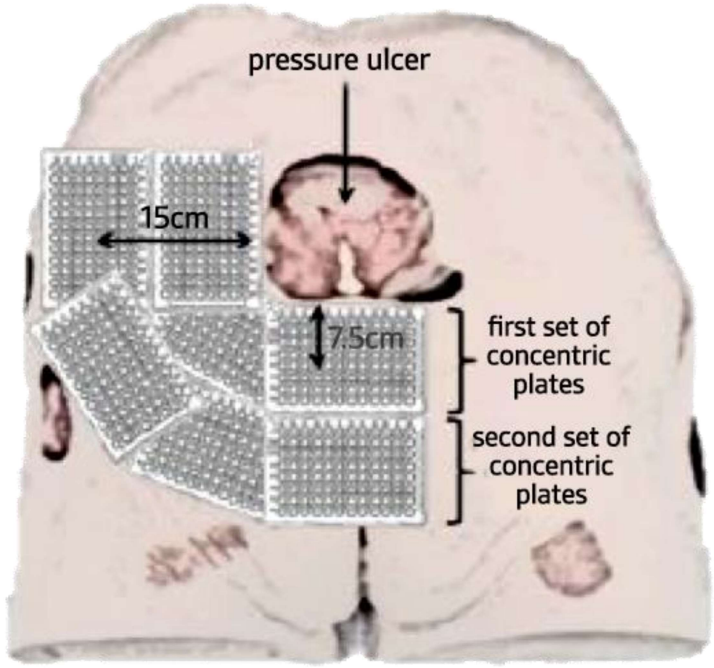
Aerosolization of wound fluid and bacteria: Solventum™ Veraflo™ Therapy vs. pulsed lavage

Benchtop wound model was:[1]

- Inoculated with wound fluid and fluorescent bacteria particles
- Cleansed with low pressure manual lavage or Veraflo Therapy
- Aerosolized bacteria were collected on concentric plates surrounding the simulated wound area



Reference: 1. Allen D, LaBarbera L, Bondre I, et al. Comparison of tissue damage, cleansing and cross-contamination potential during wound cleansing via two methods: lavage and negative pressure wound therapy with instillation. Int Wound J. 2012 Aug;11(2):198-209.

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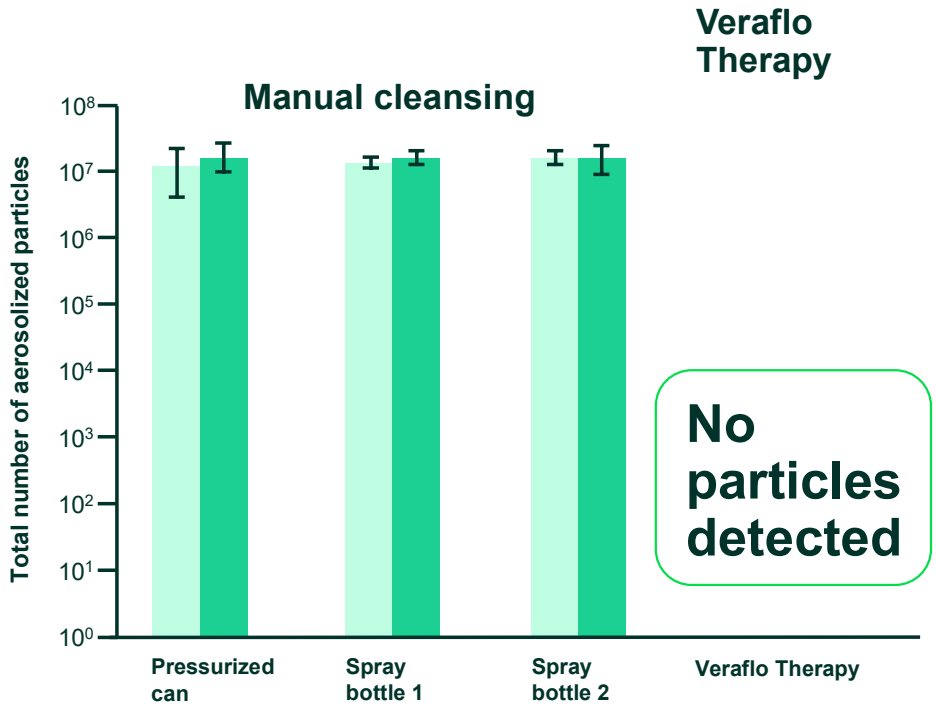
Aerosolization of wound fluid and bacteria: Solventum™ Veraflo™ Therapy vs. pulsed lavage

Study suggests Veraflo Therapy may help reduce the likelihood of cross-contamination that may occur during manual cleansing:[1]

- Low pressure lavage caused aerosolization of wound fluid bacteria more than 6 inches (15 cm) from model
- Veraflo Therapy provided controlled, contained cleansing
  - **No wound fluid bacteria detected outside the wound model**
  - Wound fluid bacteria found inside canister



Reference: 1. Allen D, LaBarbera L, Bondre I, et al. Comparison of tissue damage, cleansing and cross-contamination potential during wound cleansing via two methods: lavage and negative pressure wound therapy with instillation. Int Wound J. 2012 Aug;11(2):198-209.

Porcine granulation tissue formation:
Solventum™ V.A.C.® Therapy vs Solventum™ Veraflo™ Therapy

Negative pressure wound therapy with controlled saline instillation (NPWTi): Dressing properties and granulation response *In Vivo*.[1]

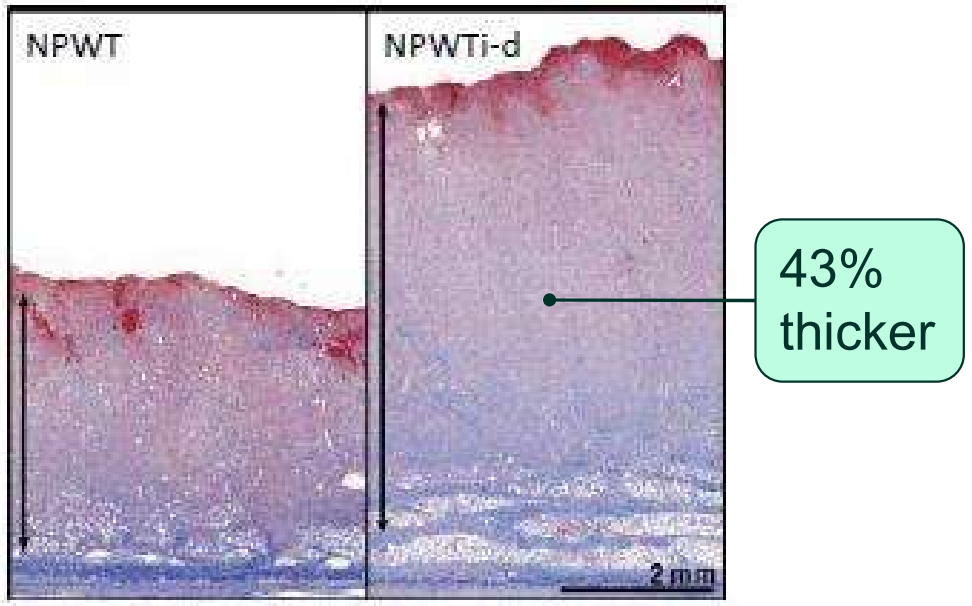
This study compared V.A.C.® Therapy vs. Veraflo Therapy in non-infected porcine model.

- Saline, 5 min dwell, 2.5 hr of V.A.C.® Therapy at -125 mmHg

- Wounds treated with Veraflo Therapy and saline had **43%** more granulation tissue than V.A.C.® Therapy wounds after 7 days of therapy

Note: These results have not been confirmed in human studies.

Granulation thickness at Day 7



Reference: 1. Allen D, LaBarbera L, Bondre I, et al. Comparison of tissue damage, cleansing and cross-contamination potential during wound cleansing via two methods: lavage and negative pressure wound therapy with instillation. Int Wound J. 2012 Aug;11(2):198-209.

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Clinical study: Comparison of outcomes for normal saline and an antiseptic solution for negative-pressure wound therapy with instillation (Kim, 2015)[1]

Authors: Kim PJ, Attinger CE, Steinberg JS, et al. *Plastic and Reconstructive Surgery*, 2015

Study type: Independent, prospective, randomized comparative effectiveness study.

Purpose: To compare the outcomes of normal saline vs. a topical wound solution for NPWTi-d for the adjunctive treatment of infected wounds.

Methods:

Treatment groups:
- Solventum™ V.A.C.® Ulta™ Therapy Unit using Solventum™ Veraflo™ Therapy **with Normal Saline** with 20 minutes of dwell and 2 hours of NPWT
- V.A.C.® Ulta Therapy Unit using Veraflo Therapy **with PHMB** with 20 minutes of dwell and 2 hours of NPWT

Patients:
- Patients whose infected wounds required hospitalization and serial surgical debridement
- All patients received parenteral antibiotics

Instillation solution: Normal Saline or Prontosan® Wound Irrigation Solution

Prontosan® is a trademark of B. Braun.

Reference: 1. Kim, PJ, et al. Comparison of outcomes for normal saline and an antiseptic solution for negative-pressure wound therapy with instillation. Plast Reconstr Surg. 2015 Nov;136(5):657e-64e.

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Clinical study results: PHMB vs. normal saline[1]

Intent to treat	Normal saline (%)	PHMB (%)	P – Value
Length of stay (days)	13.6	14.5	0.68
Time to final surgical procedure (days)	5.7	7.7	0.04
Closed/covered at discharge	42 (85.7)	47 (92.2)	0.35
Closed/covered at 30-day follow-up	34 (69)	33 (65)	0.83

Per protocol	Normal saline (%)	PHMB (%)	P – Value
Length of stay (days)	11.7	14.2	0.08
Time to FSP (days)	5.6	7.5	0.04
Closed/covered at discharge	32 (92.9)	39 (95.1)	0.99
Closed/covered at 30-day follow-up	32 (82.1)	30 (76.9)	0.90

Conclusion

Study suggests that the outcomes following Solventum™ Veraflo™ Therapy with saline are comparable to those of PHMB when using similar settings.

- The only significant difference was time to final surgical procedure which favored the saline group

Reference: 1. Kim, PJ, et al. Comparison of outcomes for normal saline and an antiseptic solution for negative-pressure wound therapy with instillation. Plast Reconstr Surg. 2015 Nov;136(5):657e-64e.

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Topical wound solutions tested and compatible for use with Solventum™ Veraflo™ Therapy

Generic solution class	Trade name(s)	Considerations for use with Veraflo Therapy
Hypochlorite-based solutions* (e.g. hypochlorous acid, sodium hypochlorite)	DAKIN'S® Solution (0.125% NaOCl), Microcyn® (0.003% HOCl), Puracyn® Plus (0.003% HOCl), Vashe® (0.025% HOCl), Anasept® (0.057% HOCl), NeutroPhase® (0.01% HOCl)	• Based on results of compatibility testing, DAKIN'S® Solution should not be used in concentrations greater than 0.125% (quarter strength) • Consider using the fewest irrigation cycles and minimizing hold times to the lowest level that is clinically relevant
Silver nitrate (0.5%)	Various	Silver nitrate is light sensitive. Protect solution container and Solventum™ Instillation Cassette tubing from light during use of silver nitrate.
Biguanides (Polyhexanide)	Prontosan® Wound Irrigation Solution	Solution container can be: • Spiked directly • Connected using a spike adapter if available • Transferred to a container having a spike port For compatibility assessment, polyhexanide solution was tested in final concentrations equal to or less than 0.1%
Lidocaine HCl	Various, e.g. Xylocaine 2%	• For compatibility assessment, lidocaine HCl was tested in final concentrations equal to or less than 0.1% in saline • Toxicity concerns may exist; consult with your pharmacist and/or prescribing physician for solution and patient-specific considerations when using lidocaine HCl as an additive to saline instillation solutions • No device-related considerations for use with Veraflo Therapy
Cationic solutions (Octenidine)	Octenilin®	For compatibility assessment, Octenilin® solution was tested in final concentrations equal to or less than 0.05% Octenidine
Isotonic solutions	Saline Solution for Irrigation USP Lactated Ringers Irrigation	May need to be connected using a spike adapter.
Acetic acid	Acetic Acid Solution for Irrigation USP	For compatibility assessment, acetic acid was tested in final concentrations equal to or less than 0.25% in sterile water.
Benzalkonium Chloride (0.1%)	Zephiran®	For compatibility assessment, benzalkonium chloride was tested in final concentrations equal to or less than 1:200,000 dilution.

* Hypochlorous acid solutions applied frequently at high concentrations can lead to significant material degradation. Consider utilizing concentrations and exposure durations as low as clinically relevant. Testing indicates that the concentration of hypochlorous acid, a preservative of the solution in the bottle, may be significantly reduced after prolonged contact with the fluid path components of the Veraflo Therapy delivery system. Due to the reactive nature of hypochlorous acid solutions, exposure to the fluid path components of the Veraflo Therapy delivery system may impact the final active or preservative concentration of the solution.
* Solventum is solely responsible for the solution compatibility information provided herein. Always refer to the solution manufacturer's prescribing information when deciding whether to administer any solution with the Solventum™ V.A.C.® Ulta™ Therapy Unit and for appropriate safety, efficacy and dosing information. Listing of specific solutions is not an endorsement of a specific solution or an indication of clinical efficacy or safety.

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Systematic literature review and meta-analysis

Effects of negative-pressure wound therapy with instillation versus standard of care in multiple wound types: Systematic literature review and meta-analysis.

Gabriel A, et al. (2021)

Reference: Gabriel A, Camardo M, O'Rorke E, Gold R, Kim PJ. Effects of Negative-Pressure Wound Therapy With Instillation versus Standard of Care in Multiple Wound Types: Systematic Literature Review and Meta-Analysis. Plast Reconstr Surg. 2021 Jan 1;147(1S-1):68S-76S. doi: 10.1097/PRS.0000000000007614. PMID: 33347065.

Systematic literature review and meta-analysis (Gabriel, 2021)

Purpose

Systemic literature review and meta-analysis to determine the effects of NPWTi-d versus control therapy in the adjunctive management of complex wounds.

Methods

Inclusion criteria	Exclusion criteria

• Peer-reviewed study was completed by Dec 31, 2019
• Population of at least 10 patients
• Comparative study that involved use of NPWTi-d (Solventum™ V.A.C.® Ulta™ Therapy Unit or Solventum™ V.A.C.® Instill Therapy System) vs. any other comparative treatment
• Must have reported at least one of the following endpoints:
  • Time to wound closure/final surgical procedure
  • Length of hospital stay
  • Number of surgical debridements
  • Number of wounds closed
  • Wound size reduction
  • Level of granulation tissue formation
  • Duration of therapy
  • Level of bacterial colonization
  • Clinical signs of infection
	• Meta-analysis and reviews
	• Preclinical studies (animal or bench)
	• Veterinary studies
	• Studies with pediatric patients
	• Instillation into the thoracic or abdominal cavity

Reference: Gabriel A, Camardo M, O'Rorke E, Gold R, Kim PJ. Effects of Negative-Pressure Wound Therapy With Instillation versus Standard of Care in Multiple Wound Types: Systematic Literature Review and Meta-Analysis. Plast Reconstr Surg. 2021 Jan 1;147(1S-1):68S-76S. doi: 10.1097/PRS.0000000000007614. PMID: 33347065.

Systematic literature review and meta-analysis (Gabriel, 2021)

Results

	Studies	Subjects/ wounds	Standardized means across studies		Effect estimate SD mean difference (95% CI)	Odds ratio (95% CI)	P- Value†
			NPWTi-d (%)	Control			
No. of surgical debridements	7	495	2.23	3.07	-0.84 (-1.51, -0.17)	N/A	0.01
Time to final surgical procedure	8	525	3.02	4.16	-1.14 (-2.17, -0.12)	N/A	0.03
Length of therapy	4	183	1.52	3.49	-1.97 (-3.75, -0.19)	N/A	0.03
No. of wounds closed	6	413	–	–	N/A	2.39 (1.22, 4.68)	0.01
Subjects with bacterial count reduction	2	86	–	–	N/A	4.40 (1.65, 11.7)	0.003
Length of hospital stay	3	254	1.17	3.28	-2.11 (-4.35, 0.13)	N/A	0.06

Reference: Gabriel A, Camardo M, O'Rorke E, Gold R, Kim PJ. Effects of Negative-Pressure Wound Therapy With Instillation versus Standard of Care in Multiple Wound Types: Systematic Literature Review and Meta-Analysis. Plast Reconstr Surg. 2021 Jan 1;147(1S-1):68S-76S. doi: 10.1097/PRS.0000000000007614. PMID: 33347065.

Systematic literature review and meta-analysis[1] (Gabriel, 2021)

Therapy outcomes[1,2]

	Standard of care	Solventum™ Veraflo™ Therapy	Difference
Time of final surgical procedure	**14.36** Days	**7.88** Days	**6.48** Fewer days
	p = .003		
Length of therapy	**21.8** Days	**9.88** Days	**11.92** Fewer days
	p = .02		
Length of hospital stay	**26.79** Days	**11.39** Days	**15.4** Fewer days
	p = .02		
Surgical debridements	**2.69** Debridements	**1.77** Debridements	**0.92** Debridements
	p = .008		

Wounds were **2.39 times** more likely to close than standard of care

Reduced time to final surgical procedures by almost half

Reduced length of therapy by over a week

Reduced length of hospitalization by over 2 weeks

>30% fewer surgical debridements

.

1. Gabriel, Allen MD, FACS; Camardo, Mark MS; O'Rorke, Erin BS; Gold, Rebecca BS; Kim, Paul J. DPM, MS, FACFAS Effects of Negative-Pressure Wound Therapy With Instillation versus Standard of Care in Multiple Wound Types: Systematic Literature Review and Meta-Analysis, *Plastic and Reconstructive Surgery*: January 2021 - Volume 147 - Issue 1S-1 - p 68S-76S doi: 10.1097/PRS.0000000000007614. **2.** Camardo, Mark. "Veraflo Meta-Analysis Standardized and Non-Standardized Means.", Internal Report, San Antonio, Texas, 2020 .

Systematic literature review and meta-analysis (Gabriel, 2021)

Health economic impact

An economic analysis of the Gabriel et al. meta-analysis[1] with non-standardized means[2] illustrates potential cost effectiveness for Solventum™ Veraflo™ Therapy

Veraflo Therapy sample health economic model

Reduction in debridements

Reduction in total therapy costs

Total cost of care savings (not including length of stay)

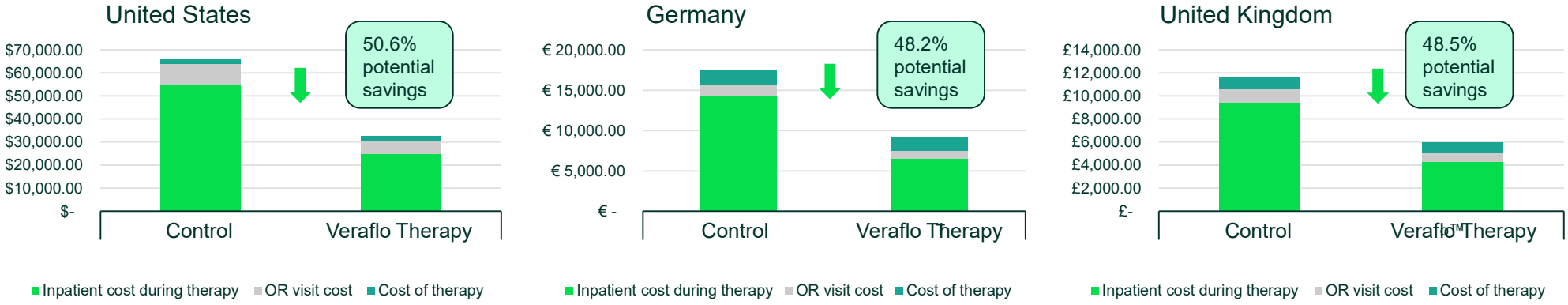
	Standard of care	Potential reduction	Veraflo Therapy
Trips to OR for debridement	2.69	34%	1.77
Mean cost of OR debridement	$3,393		$3,393
Total OR debridement cost (trips x cost)	$9,127	34%	**$6,005**
Time to final surgical procedure (days)	14.36	45%	7.88
Length of therapy (days)	21.8	55%	9.88
Daily cost of therapy[3]	$94		$143
Total therapy costs (days x daily cost)	$2,070	32%	**$1,141**
Total cost per patient	**$11,197**	**34%**	**$7,420**
Potential savings due to fewer trips to OR			**$3,121**
Potential savings due to shorter length of therapy			**$655**
Total potential savings per patient			**$3,777**

1. Gabriel, Allen MD, FACS; Camardo, Mark MS; O'Rorke, Erin BS; Gold, Rebecca BS; Kim, Paul J. DPM, MS, FACFAS Effects of Negative-Pressure Wound Therapy With Instillation versus Standard of Care in Multiple Wound Types: Systematic Literature Review and Meta-Analysis, *Plastic and Reconstructive Surgery*: January 2021 - Volume 147 - Issue 1S-1 - p 68S-76S doi: 10.1097/PRS.0000000000007614. **2** Camardo, Mark. "Veraflo Meta-Analysis Standardized and Non-Standardized Means.", 3M Internal Report, San Antonio, Texas, 2020 **3.**Davies DG, Geesey GG. Regulation of the Alginate Biosynthesis Gene algC in Pseudomonas aeruginosa during Biofilm Development in Continuous Culture. Appl Environ Microbiol. 1995; 61(3):860-867.

Economic model to estimate cost of negative pressure wound therapy with instillation vs. control therapies for hospitalized patients in the United States, Germany, and United Kingdom

Kim PF, Lookess S, Bongards C, Griffin L, Gabriel A

Summary: This study analyzed the potential cost savings of using Solventum™ Veraflo™ Therapy in three countries based upon the findings of the Gabriel et al. meta-analysis published in Plastic and Reconstructive Surgery - January Supplement 2021.



Conclusion: Use of Veraflo Therapy compared to control potentially provides approximately 50% savings through reductions in OR visits, therapy costs and inpatient costs during therapy. Potential savings was shown in three separate countries with different healthcare systems and costs: U.S., Germany, and U.K.

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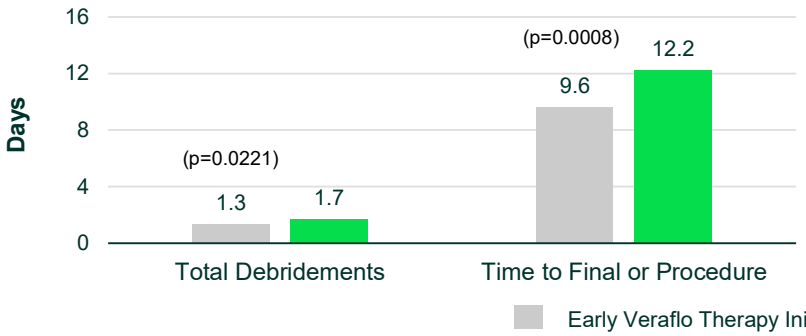
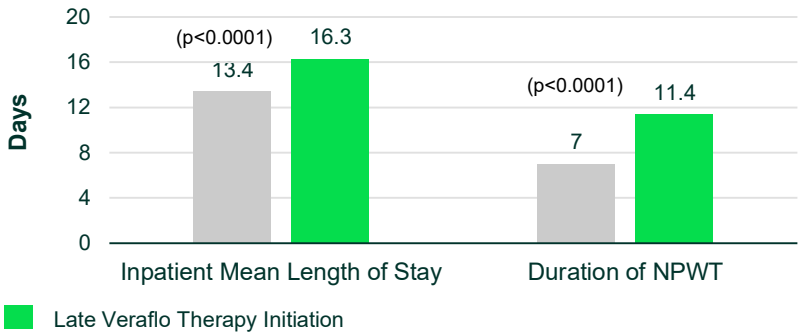
The effect of timing of Solventum™ Veraflo™ Therapy on outcomes and costs for patients receiving negative pressure wound therapy[1]

Summary: A retrospective analysis of a national, all-payer hospital database of patients who received Veraflo Therapy in 2019 suggests that **early use of Veraflo Therapy** (within 1 day of NPWT application) compared **to late initiation of Veraflo Therapy** (within 2-7 days of NPWT application) **can help improve clinical outcomes and reduce cost of care.**

Total Debridements and Time to Final OR Procedure, mean (SD)



Length and Stay and Duration of NPWT, mean (SD)



- Patients who received Veraflo Therapy on Day 1 had fewer wound-related readmissions than patients with late initiation **(6 vs.16 at 30 days; p=0.0293 and 10 vs. 24 at 60 days p=0.0130)**
- The mean total cost of index admissions was $10,877 less for patients who received Veraflo Therapy on Day 1 than patients with late initiation **($34,161 vs $45,038: p <0.0001)**
- The total NPWT cost during hospitalization was $935 less when Veraflo Therapy was initiated on Day 1 than patients with late initiation **($1,020 vs. $1,955; p=0.0001)**

1. Collinsworth AW, Griffin LP. The effect of timing of instillation therapy on outcomes and costs for patients receiving negative pressure wound therapy. Wounds. 2022;34(11):269-275. doi:10.25270/wnds/22013

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3M™ Veraflo™ Cleanse Choice Complete™ Dressing

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HCP clinical challenges

Market research conducted in 2015* suggested:

- ~26% of patients needing debridement are not appropriate for OR surgical debridement
- OR surgical debridement can lead to over-excision and wound damage
- Patients are often bumped from the OR due to prioritization/severity of their wounds and end up on a temporizing treatment

Wet slough†

Local infection of the wound and wound edges, with the potential presence of a biofilm‡

*Based on 20 physician surveys from ACS, ACOS & ASPS, 2015

† Patient photo courtesy of John Stuchbury, Albury Base Hospital, Albury, NSW

‡ Patient photo courtesy of Mark Keating, Wound CNC, Camden & Campbelltown Hospital, Campbelltown, NSW

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Potential clinical benefits:
3M™ Veraflo™ Cleanse Choice Complete™ Dressing

- The Veraflo Cleanse Choice Complete Dressing, when used with Solventum™ Veraflo™ Therapy, can be used to initiate immediate wound cleansing therapy
- Hydromechanically remove nonviable tissue**, reducing the number of surgical debridements required***
- Easy application with flexibility

* Veraflo Therapy with Veraflo Cleanse Choice Complete Dressing provides hydromechanical removal of non-viable tissue and wound debris, which reduces the number of surgical debridements required, while promoting granulation tissue formation, creating an environment that promotes wound healing.

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3M™ Veraflo™ Cleanse Choice Complete™ Dressing

Contact layer
18 cm x 12.5 cm x 0.8 cm
1.0 cm circular holes
5 mm spacing

Smooth cover layer
18 cm x 12.5 cm x 0.8 cm

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Why the 1 cm holes?

What needed to happen

Dressing to provide “mechanical” movement at the wound surface in combination with cyclic delivery and dwell of topical solutions to help loosen thick exudate and loosen wound debris for removal during the Solventum™ V.A.C.® Therapy phase.

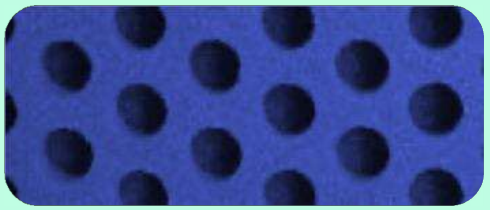
Design concepts

Modified 3M™ Veraflo Cleanse Choice Complete™ Dressing to include a pattern of through holes to facilitate lateral dressing movement during V.A.C.® Therapy phase.

Concepts included the following

- Pattern of circles
- Pattern of hexagons
- Pattern of ovals

Most mechanical movement



Circles

Hexagons

Ovals

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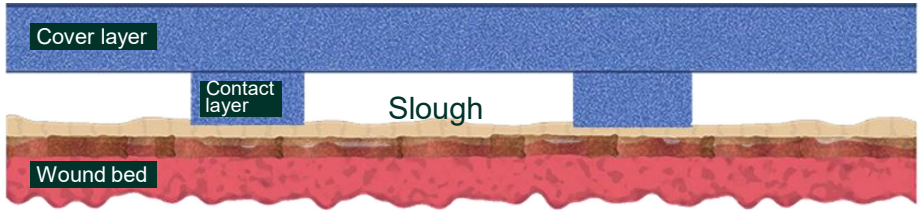
3M™ Veraflo™ Cleanse Choice Complete™ Dressing

Proposed mechanism of action,[1] dressing at application

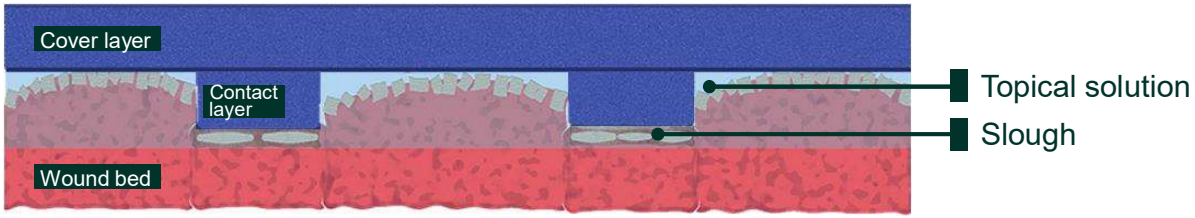
Occlusive drape



Non-compressed dressings (no negative pressure applied).

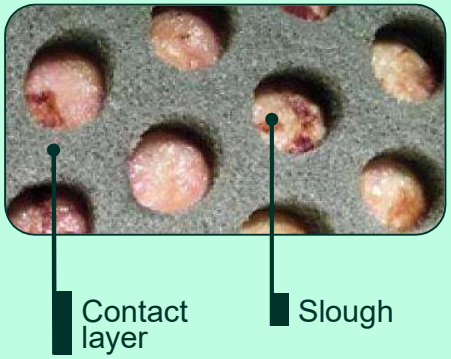
Wound bed during instillation/dwell phase

Occlusive drape



Non-compressed dressings (after negative pressure applied, with topical solution instilled).

Reference: 1. Kim PJ, Applewhite A, Dardano AN et al. Use of a novel foam dressing with negative pressure wound therapy and instillation: recommendations and clinical experience. WOUNDS. 2018;30:S1-S17.



Softening
Solubilizing
Separating[1]

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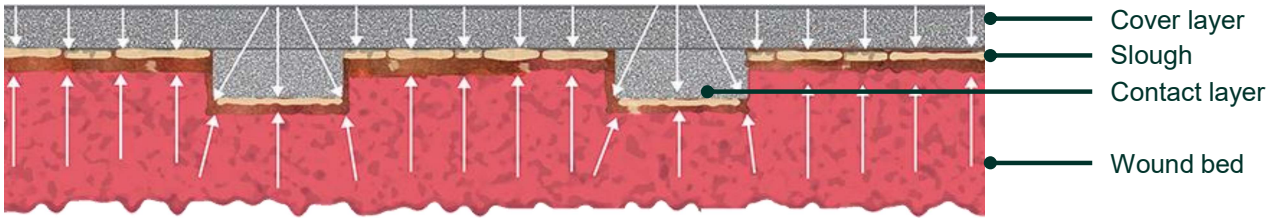
3M™ Veraflo™ Cleanse Choice Complete™ Dressing

Proposed mechanism of action,[1] wound bed during Solventum™ V.A.C.® Therapy

Occlusive drape



Compressed Veraflo Cleanse Choice Complete Dressing (negative pressure applied).

Wound at dressing change

1-3 dressing changes

Wound bed at dressing change: devitalized tissue more concentrated on tops of macro-columns vs. base of wound.

Reference: 1. Kim PJ, Applewhite A, Dardano AN et al. Use of a novel foam dressing with negative pressure wound therapy and instillation: recommendations and clinical experience. WOUNDS. 2018;30:S1-S17.

"Cyclic delivery of the solution, as well as the dwell time and removal of the solution, is hypothesized to produce a **mechanical hydrodynamic force** on the stressed wound bed, disrupting and helping to soften and solubilize thick exudate and loosen wound debris for removal during NPWT."[1]

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Clinical study: Teot (2017)

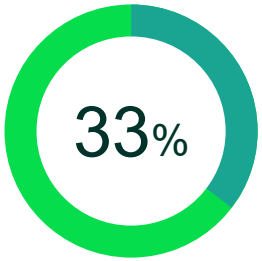
Novel foam dressing using negative pressure wound therapy with instillation to facilitate removal of thick exudate.

Solventum™ Veraflo Cleanse Choice™ Dressing

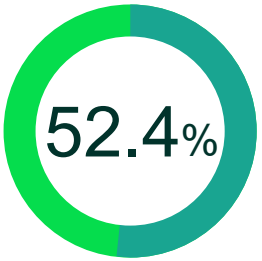
Clinical study: Novel foam dressing using negative pressure wound therapy with instillation to remove thick exudate. (Teot, 2017)[1]

Methods: A retrospective data analysis on 21 patients with 21 large complex wounds that contained substantial areas of devitalized tissue and/or yellow fibrinous slough were treated in one hospital by several surgeons. Wounds presented with various range of clinical situations including hard-to-heal wounds and necrotic and/or fibrinous tissue on the wound surface.

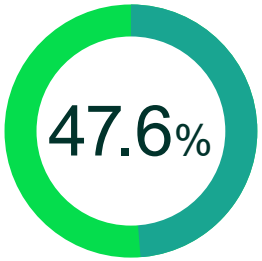
Patients:



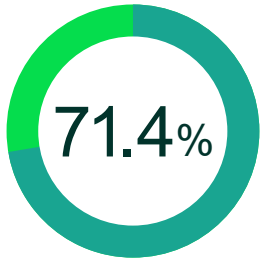
(7/21) received conventional **NPWT prior** to Solventum™ Veraflo™ Therapy



(11/21) received **surgical debridement prior** to Veraflo Therapy



(10/21) **did NOT receive surgical debridement prior** to Veraflo Therapy



(15/21) had a confirmed and treated bone infection

Therapy settings:

- **Solution:** Normal Saline
- **Dwell time:** 10 minutes
- **NPWT time:** 3.5 hours
- **Pressure setting:** -125 mmHg
- **Dressing:** Solventum™ Veraflo Cleanse Choice™ Dressing

Reference: 1. Teot L., Boissiere F., Fluieraru, S. Novel foam dressing using negative pressure wound therapy with instillation to remove thick exudate Int Wound J. 2017; 10:1111/iwj.12719.

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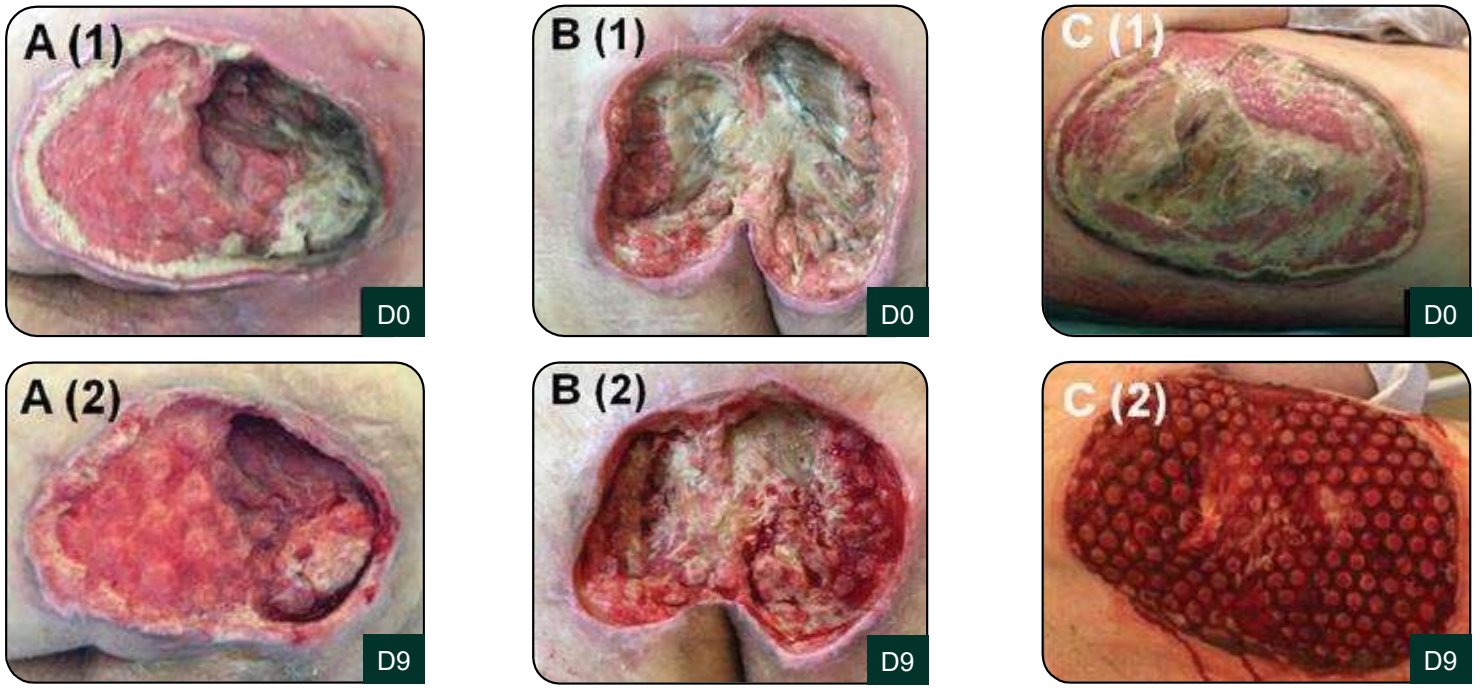
Representative cases after 9 days of Solventum™ Veraflo™ Therapy[1]



Note: No debridement performed during dressing changes.

Reference: 1. Teot L., Boissiere F., Fluieraru, S. Novel foam dressing using negative pressure wound therapy with instillation to remove thick exudate Int Wound J. 2017; 10:1111/iwj.12719.

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Clinical results: Teot, 2017[1]

Solventum™ Veraflo Cleanse Choice™ Dressing assisted in loosening, solubilising and detaching viscous exudate, dry fibrin, wet slough and other infectious materials. Results of this analysis showed that after three days, the majority of the fibrinous material and slough present in the wound bed was removed during therapy.

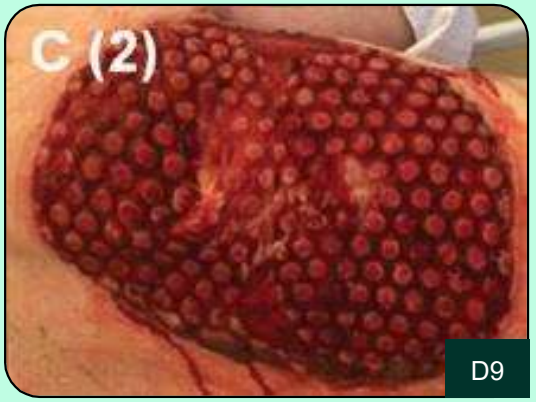
Cleaning

- **85.7%** wounds (18/21) had **≤ 10% surface area with black non-viable tissue** remaining after an average of 1-3 applications (3-9 days of therapy).
- **57.1%** wounds (12/21) had **≤ 10% surface area with yellow fibrinous slough** remaining after an average of 1-3 applications (3-9 days of therapy).

Granulation

- **95.2%** wounds (20/21) displayed **rapid granulation tissue formation** under the portion of the foam directly in contact with the wound bed.

Note: This analysis has all the limitations of an uncontrolled case series including selection biases and lack of consideration of confounding variables.



Reference: 1. Teot L., Boissiere F., Fluieraru, S. Novel foam dressing using negative pressure wound therapy with instillation to remove thick exudate Int Wound J. 2017; 10:1111/iwj.12719.

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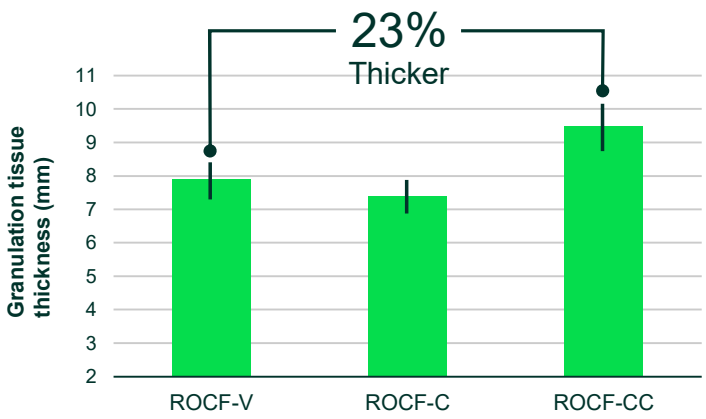
Pre-clinical results: granulation tissue formation

Porcine study: Solventum™ Veraflo™ Dressing vs. Solventum™ Veraflo Cleanse Choice™ Dressing

Comparison of a dressing with through holes to alternative reticulated open cell foam dressings in a porcine model with slough and treatment with negative pressure wound therapy with instillation (Carroll, 2017).[1]

- This study compared Veraflo Dressing vs Veraflo Cleanse Choice Dressing in slough covered porcine models
  - Saline, 10 minutes dwell, 3.5 hours of Solventum™ V.A.C.® Therapy at -125 mmHg
- Wounds treated with Veraflo Cleanse Choice Dressing had **23% thicker granulation tissue** than Veraflo Dressing wounds after 11 days of therapy

Granulation thickness at day 11



Note: These results have not been confirmed in human studies.

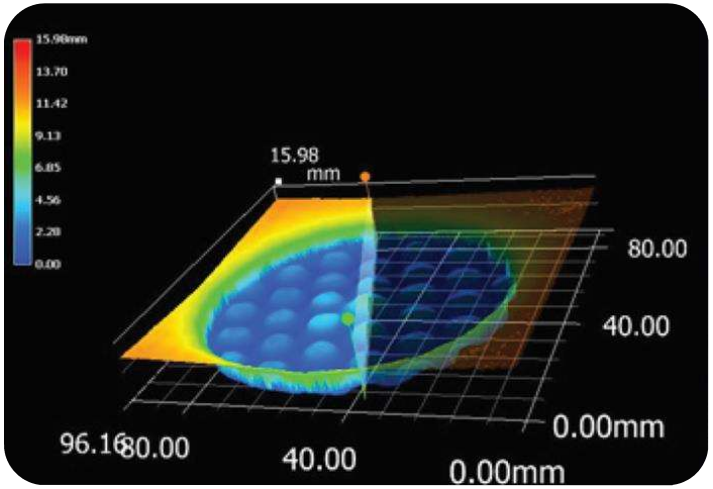
Reference: 1. Carroll C A, Kilpadi D, Ingram S. Comparison of a Dressing with Through Holes to Alternative Reticulated Open Cell Foam Dressings in a Porcine Model with Slough and Treatment with Negative Pressure Wound Therapy with Instillation. Poster presented at the Symposium on Advanced Wound Care, October 20-22, 2017; Las Vegas, NV.

Pre-clinical results: granulation tissue formation (continues from previous slide)

Porcine study: A novel dressing design—granulation, slough disruption, and mechanism of action[1]

- This study suggests that porcine wounds treated with Solventum™ Veraflo™ Therapy and saline using Solventum™ Veraflo Cleanse Choice™ Dressing with through holes may have improved healing characteristics as evidenced by more robust granulation than wounds treated with Veraflo Therapy and saline using either Veraflo Cleanse Dressing without holes or Solventum™ Veraflo™ Dressing
- Veraflo Cleanse Choice Dressing exhibits a unique strain profile under NPWT in vitro that could help expand benefits of Veraflo Therapy

Note: These results have not been confirmed in human studies.



Digital imaging of frozen Dermasol underneath Veraflo Cleanse Choice Dressing visualizing unique 3D strain profile.

Dermasol is a trademark of California Medical Innovations.

Reference: 1. Carroll C A, Kilpadi D, Ingram S. Comparison of a Dressing with Through Holes to Alternative Reticulated Open Cell Foam Dressings in a Porcine Model with Slough and Treatment with Negative Pressure Wound Therapy with Instillation. Poster presented at the Symposium on Advanced Wound Care, October 20-22, 2017; Las Vegas, NV.

Soventum™ Veraflo™ Therapy with Soventum™ Veraflo Cleanse Choice™ Dressing

Clinical case summaries

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Clinical case summary: Sacral pressure injury

A 64-year-old male presented with a stage 4 pressure injury of the sacrum present for more than 4 years. Patient comorbidities included former tobacco use, poor nutritional status, hypertension, chronic paraplegia (present for more than 15 years), leukocytosis, multiple previous pressure injuries, and osteomyelitis of the sacrum. The wound had been previously treated with NPWT, offloading, silver dressings, air mattress use, hydrofiber dressings, alginate dressings, and wound debridement. Bedside sharp debridement was performed but limited by inability to achieve adequate hemostasis.

Day 0: Solventum™ Veraflo Cleanse Choice™ Dressing with Solventum™ Veraflo™ Therapy was applied.

Day 3: Wound at first dressing change. Significant reduction in non-viable tissue and rapid increase in granulation tissue formation noted.

- **Instillation solution:** Saline
- **Dwell time:** 1 minute
- **Negative pressure time:** 30 minutes
- **Pressure setting:** -150 mmHg
- **Dressing changes:** 48-72 hours

Patient information courtesy of Kimberly D. Hall, DNP, RN, GCNS-BC, CWCN-AP, COCN and Jessica Patterson, BSN, RN, CWOCN Roanoke, VA

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Clinical case summary: Infected AKA stump

A 33-year-old male. Comorbidities included tobacco use, anemia, and a history of methicillin-resistant Staphylococcus aureus infection. Conservative sharp debridement was performed at the bedside, and oral antibiotics were initiated.

Day 0: Infected above-the-knee (AKA) amputation stump. Solventum™ Veraflo Cleanse Choice™ Dressing with Solventum™ Veraflo™ Therapy was applied.

Day 3: Wound after dressing change. Significant reduction in non-viable tissue and rapid increase in granulation tissue formation noted.

- **Instillation solution:** Hypochlorous solution
- **Dwell time:** 10 minutes
- **Negative pressure time:** 2 hours
- **Pressure setting:** -125 mmHg
- **Dressing changes:** 48-72 hours

Patient information courtesy of Kimberly D. Hall, DNP, RN, GCNS-BC, CWCN-AP, COCN and Jessica Patterson, BSN, RN, CWOCN Roanoke, VA

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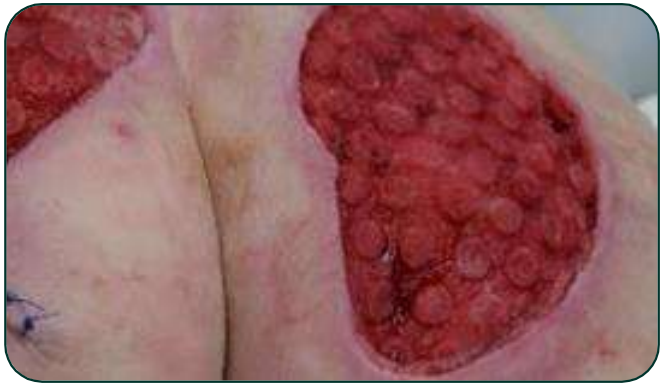
Clinical case summary: Contact burns to the bilateral buttocks

A 61-year-old female with full thickness contact burns to the bilateral buttocks was taken to the operating room for debridement. After debridement, Solventum™ Veraflo Cleanse Choice™ Dressing with Solventum™ Veraflo™ Therapy with was used to help promote granulation tissue and prep for skin grafts. Both grafts had 100% take.

Day 0: Wound at presentation.



Day 3: Wound after debridement and one Veraflo Cleanse Choice Dressing.

- **Instillation solution:** Hypochlorous solution
- **Dwell time:** 20 minutes
- **Negative pressure time:** 3 hours
- **Pressure setting:** -125 mmHg
- **Dressing changes:** 48-72 hours

Patient data and photos courtesy of Marc R Matthews, MD; Aaron Hechtman, MD; Asia N. Quan, MD; Kevin N. Foster, MD; Luis G. Fernandez, MD, KHS, KCOEG, FACS, FASAS, FCCP, FCCM, FICS

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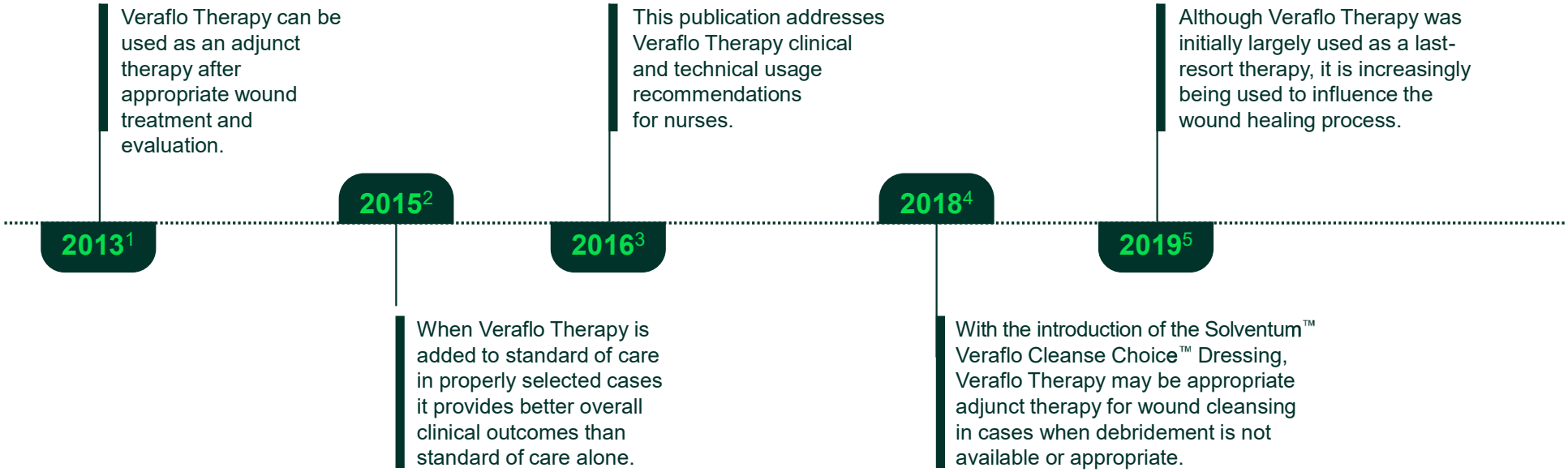
Expert consensus recommendations for use of Solventum™ Veraflo™ Therapy

Evolution through the years



References: 1. Kim, PJ, et al. Negative pressure wound therapy with instillation: international consensus guidelines. Plast Reconstr Surg. 132.6 (2013): 1569-79. **2.** Kim, PJ, Attinger, CE, Olawoye O, Crist BD, Gabriel A, Galiano RD, Teot L. Negative pressure wound therapy with instillation: review of evidence and recommendations. WOUNDS. 2015 Dec; 27(12), S2-S19. **3.** McKanna M, Geraci J, Hall K et al. Clinical panel recommendations for use of negative pressure wound therapy with instillation. Ostomy Wound Manage. 2016 Apr; 62(4):S1-S14. **4.** Kim PJ, Applewhite A, Dardano AN, et al. Use of a novel foam dressing with negative pressure wound therapy and instillation: recommendations and clinical experience. WOUNDS. 2018 Mar; 30(3 suppl):S1-S17. **5.** Kim PJ, Attinger CE, Constantine T, et al. Negative pressure wound therapy with instillation: International consensus guidelines update. Int Wound J. epub Oct 30, 2019. https://doi.org/10.1111/iwj.13254. **6.** Collinsworth AW, Griffin LP. The effect of timing of instillation therapy on outcomes and costs for patients receiving negative pressure wound therapy. Wounds. 2022;34(11):269-275. doi:10.25270/wnds/22013 *K221585

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2019 multidisciplinary consensus recommendations for use of Solventum™ Veraflo™ Therapy[1]

The following recommendations are based on the following publication: Kim et al. (2019)

Negative pressure wound therapy with instillation: International consensus guidelines update. International Wound Journal. 10.1111/iwj.13254. These recommendations may be used to guide the appropriate use of Veraflo Therapy in conjunction with Solventum™ V.A.C.® Ulta™ Therapy Unit safety information.

Note: Veraflo Therapy is not indicated for treatment of infection, for the prevention and treatment of biofilm, or for the delivery of non-topical antibiotics or drugs.

Reference: 1. Kim PJ Attinger, CE, Constantine T, et al. Negative pressure wound therapy with instillation: International consensus guidelines update. Int Wound J. 2019; 1–13.

2019 multidisciplinary consensus recommendations for use of Solventum™ Veraflo™ Therapy[1]

Appropriate wound types for Veraflo Therapy

In conjunction with appropriate wound care, such as debridement and systemic antibiotics, Veraflo Therapy may be used as an adjunct therapy in the following acute, and chronic wound types:

- Traumatic wounds
- Diabetic wounds
- Venous leg ulcers
- Pressure injuries/ulcers
- Surgical, including dehisced, wounds
- Wounds with exposed intact bone
- Wounds with treated, underlying osteomyelitis
- Infected or contaminated wounds in the presence of orthopedic fixation hardware
- Full-thickness burns after excision
- Wounds resulting from evacuation of a hematoma and when hemostasis is achieved
- Wounds that are a bridge between staged/delayed amputation

Reference: 1. Kim PJ Attinger, CE, Constantine T, et al. Negative pressure wound therapy with instillation: International consensus guidelines update. Int Wound J. 2019; 1–13.

2019 multidisciplinary consensus recommendations for use of Solventum™ Veraflo™ Therapy[1]

Appropriate wound characteristics for Veraflo Therapy

In conjunction with appropriate wound care, such as debridement and systemic antibiotics, Veraflo Therapy with Solventum™ Veraflo™ Dressing may be considered for use in wounds with the following characteristics:

- Clean wounds
- Contaminated/infected wounds
- Wounds with heavy bioburden
- Wounds that are difficult to granulate
- Adequately cleansed and debrided wounds

Reference: 1. Kim PJ Attinger, CE, Constantine T, et al. Negative pressure wound therapy with instillation: International consensus guidelines update. Int Wound J. 2019; 1–13.

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2019 multidisciplinary consensus recommendations for use of Solventum™ Veraflo™ Therapy[1]

Appropriate wound characteristics for Solventum™ Veraflo Cleanse Choice™ Dressing

In conjunction with appropriate wound care, such as debridement and systemic antibiotics, Veraflo Therapy with Solventum™ Veraflo™ Dressing may be considered for use in wounds with the following characteristics:

- Contaminated/infected wounds
- Wounds with heavy bioburden
- Wound beds that contain thick exudate
- Wounds that could benefit from wound cleansing when sharp debridement is delayed or not an option
- Wounds that contain ≥ 40% surface area coverage with clean healthy and viable tissue

Reference: 1. Kim PJ Attinger, CE, Constantine T, et al. Negative pressure wound therapy with instillation: International consensus guidelines update. Int Wound J. 2019; 1–13.

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2019 multidisciplinary consensus recommendations for use of Solventum™ Veraflo™ Therapy[1]

Appropriate Solventum™ V.A.C.® Therapy phase

- 2.0 to 3.0 hours with Solventum™ Veraflo™ Dressing
- 2.0 to 2.5 hours with Solventum™ Veraflo Cleanse Choice™ Dressing

Appropriate pressure setting

- -125 mmHg

Appropriate dwell time setting

- 10 minutes

Reference: 1. Kim PJ Attinger, CE, Constantine T, et al. Negative pressure wound therapy with instillation: International consensus guidelines update. Int Wound J. 2019; 1–13.

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2019 multidisciplinary consensus recommendations for use of Solventum™ Veraflo™ Therapy[1]

Where to use Veraflo Therapy with caution

- Wounds that contain appropriately protected vessels or organs, tendons, ligaments, and nerves
- Wounds with explored tunnels and/or areas of undermining

Where Veraflo Therapy is not recommended

- Wounds with presence of exposed, unprotected organs and vessels
- Wounds with presence of undrained abscess(es)
- Over split-thickness skin grafts or dermal substitutes
- Acutely ischaemic wounds

Where Solventum™ Veraflo Cleanse Choice™ Dressing are not recommended

- Wounds that contain approximately 100% surface area coverage with dry intact eschar
- Wounds with presence of exposed, unprotected organs and vessels
- Wounds with presence of undrained abscess(es)
- Wounds that measure less than 1×1 cm in size
- Over split-thickness skin grafts or dermal grafts (eg, autograft, allograft, xenograft, synthetic)

When to discontinue Veraflo Therapy

- Wound is deemed ready for surgical closure or coverage
- Wound is clinically stable for standard negative pressure wound therapy (NPWT) or other advanced therapy to be applied
- Clinical goals are met
- Wound has decompensated

Reference: 1. Kim PJ Attinger, CE, Constantine T, et al. Negative pressure wound therapy with instillation: International consensus guidelines update. Int Wound J. 2019; 1–13.

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3M™ Veraflo™ Cleanse Choice Complete™ Dressing

Application instructions

Refer to the 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit safety information and application instructions before use.

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Wound assessment and foam placement

3M™ Veraflo™ Cleanse Choice Complete™ Dressing

- Observe wound for tunneling and undermining
- Protect sensitive structures, vessels, and organs as needed
- Cut the foam to fill explored tunnels and undermining
- Cut foam as needed to allow gentle placement into the wound without firm packing of the foam, or overlapping onto intact skin
- Gently place foam into wound cavity with hole-side down, touching the base of the wound. Do not tightly pack the dressings into the wound

Caution:

- Do not cut or tear the foam over the wound

Note:

- Dressings should be changed every 48-72 hours, but no less than three times per week, with frequency adjusted by the clinician as appropriate
- Do not cut dressing over wound bed
- Do not pack foam into wound
- Do not use the Wound Contact layer with holes in tunnels or undermined areas
- Refer to Instructions For Use for complete instructions

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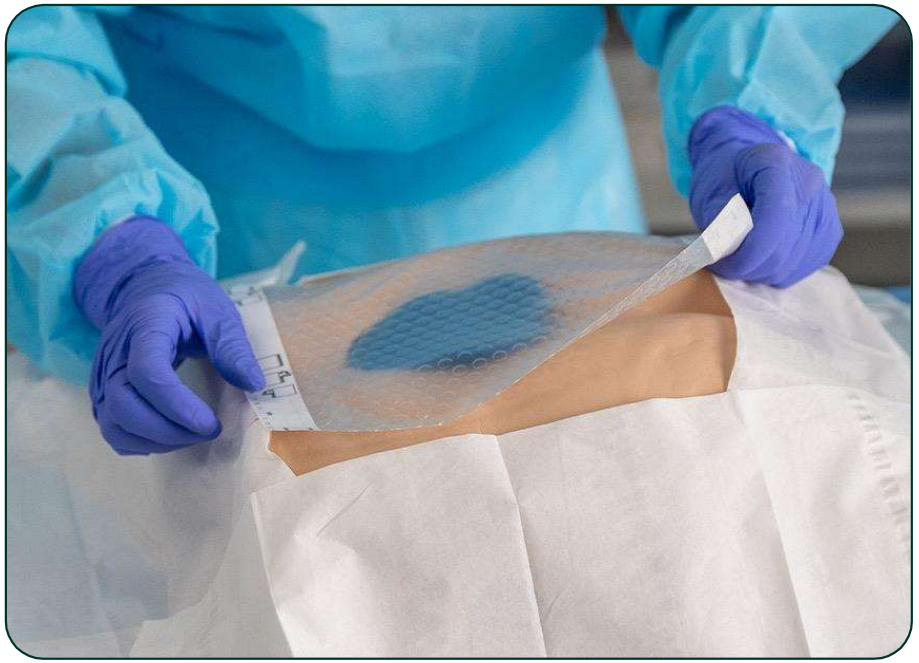
Solventum™ Dermatac™ Drape application

- Trim the drape to cover the foam at least an additional 5-7 cm border of intact periwound tissue
- Remove the release liner #1 to expose adhesive. The drape may be held by the handling bars
- Place the adhesive face down over foam and apply drape to cover foam and intact skin, ensuring drape covers at least 5-7 cm border of intact periwound tissue
- Remove the Ruler/Handling Bars

Refer to instructions for use for complete instructions.



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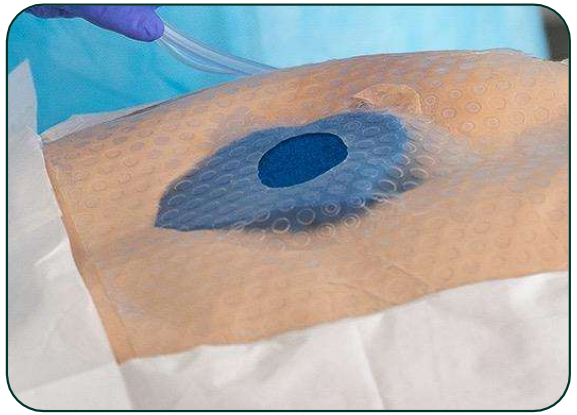
Applying the Solventum™ VeraT.R.A.C.™ Pad

- Choose pad application site. Give particular consideration to tubing positioning to allow for optimal flow, and avoid placement over bony prominences or within creases in the tissue
- Pinch drape and cut an approximately 2.5 cm hole through the drape to affix the VeraT.R.A.C. Pad
- Remove both backing Layers #1 and #2 to expose adhesive
- Position and apply the VeraT.R.A.C. Pad in a functional position for patient over the 2.5 cm hole
- Pull back on blue tab to remove pad stabilization layer



Refer to instructions for use for complete instructions.

Note: If using the Solventum™ VeraT.R.A.C. Duo™ Tube Set, please refer to Veraflo Cleanse Choice Dressing Application Instructions.

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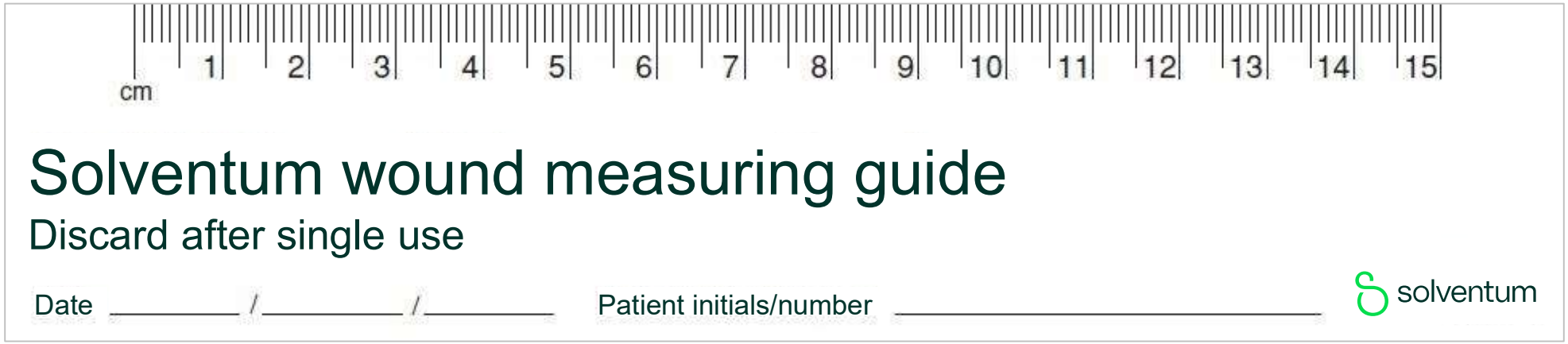
Count and record all foam pieces

- Label wound dressing and record number of pieces in patient's chart pursuant to applicable facility protocol
- Initiate prescribed Solventum™ Veraflo™ Therapy



Refer to instructions for use for complete instructions.

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Solventum™ V.A.C.® Ulta™ Therapy Unit provides Solventum™ Veraflo™ Therapy with automated, volumetric fluid delivery

Solventum™ V.A.C.® Canister

Solution container hanger arm

Solventum™ Instillation Cassette

Large interface screen
Intuitive, easy to use menu for simplified therapy programming.

Hanger arm

Volumetric fluid delivery
Utilizing a pump for reliable fluid delivery differs from other NPWT systems that provide instillation solutions under continuous flow or use gravity to instill solutions.

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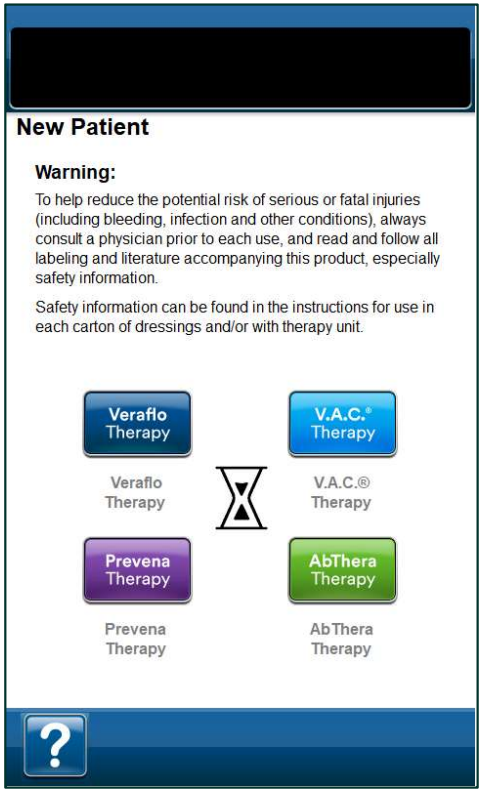
Solventum™ V.A.C.® Ulta™ Therapy System: Initiating Solventum™ Veraflo™ Therapy with the Solventum™ Smart Instill™ Feature

1



Select Veraflo Therapy to configure the therapy unit for use with Veraflo Therapy.

Note: Refer to the User Manual and Safety Information provided with the V.A.C.® Ulta Therapy Unit for complete instructions for use.

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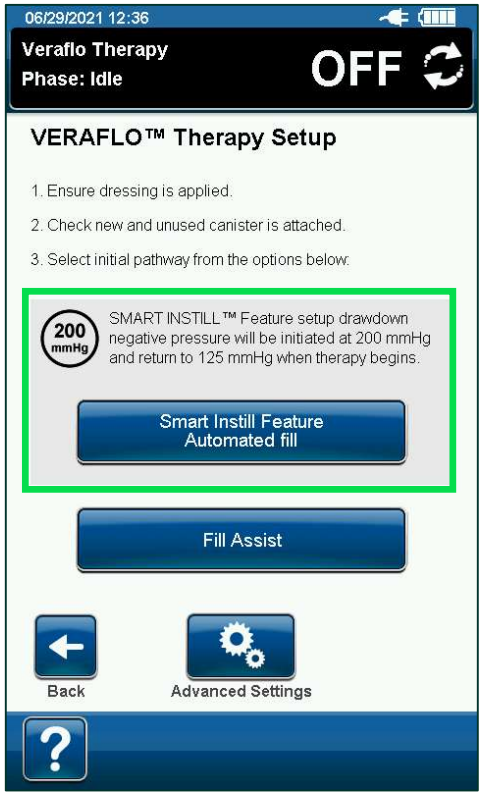
Solventum™ V.A.C.® Ulta™ Therapy Unit: Solventum™ Smart Instill™ Feature

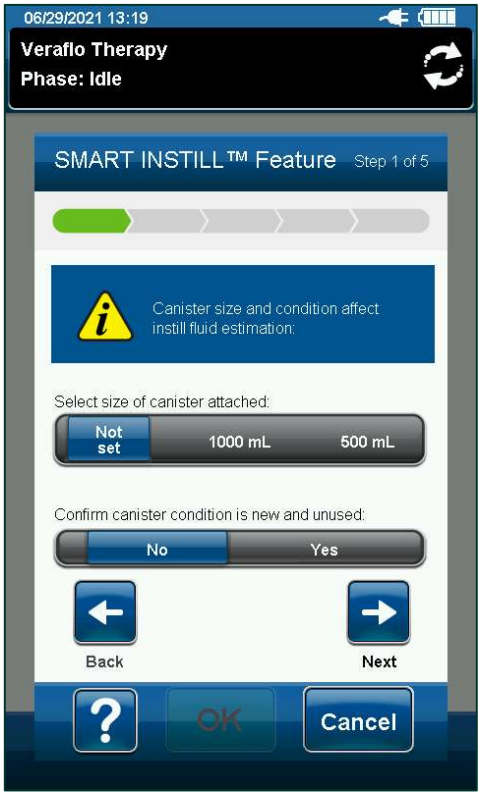
2



Smart Instill Feature - step 1

Select Smart Instill Feature.

3



Select Canister Size and confirm canister is new and unused.

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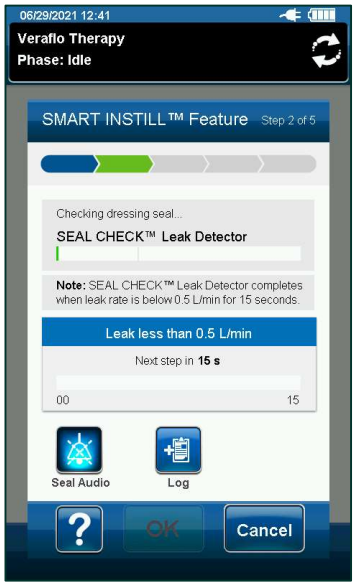
Solventum™ V.A.C.® Ulta™ Therapy Unit: Solventum™ Smart Instill™ Feature

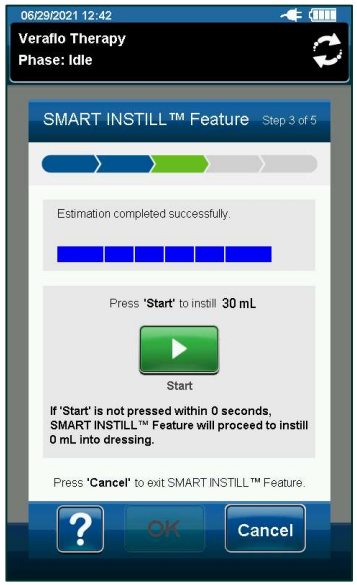
4



Step 4

Smart Instill Feature will initiate the Solventum™ Seal Check™ Feature.

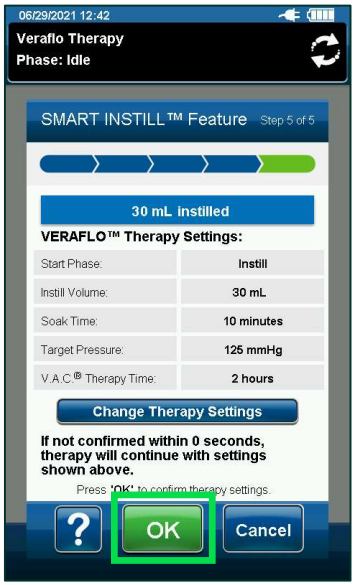
5



Step 5

The Smart Instill Feature screen will estimate and display the recommended instillation volume. If the user does not select Start, the Smart Instill Feature will automatically instill displayed instillation volume after 10 seconds.

6



Step 6

Select OK to accept the suggested settings. Solventum™ Veraflo™ Therapy will begin automatically with settings displayed if user does not select OK after 10 minutes.

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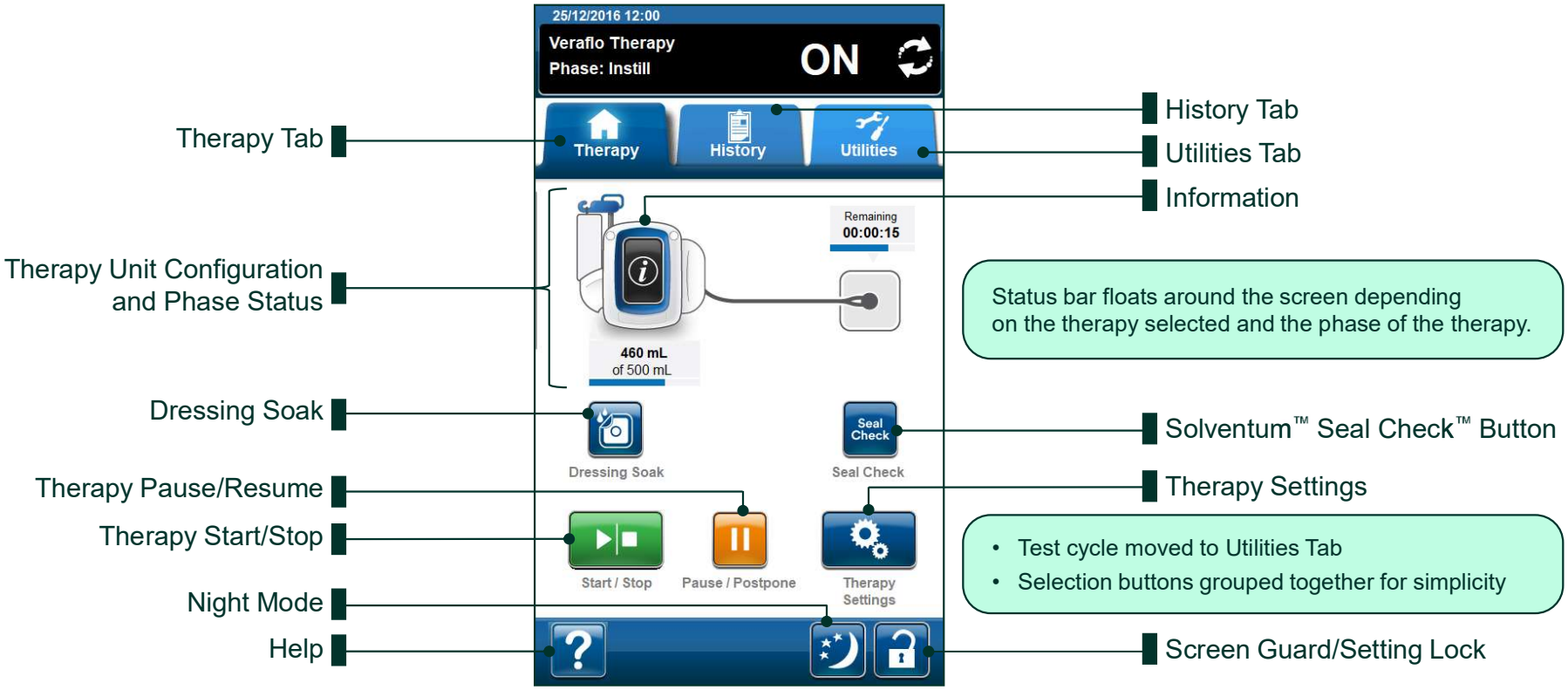
Solventum™ V.A.C.® Ulta™ Therapy Unit: Home screen

The Home screen is the main screen displayed by the unit during Solventum™ Veraflo™ Therapy. It is used to access important information about the therapy status.



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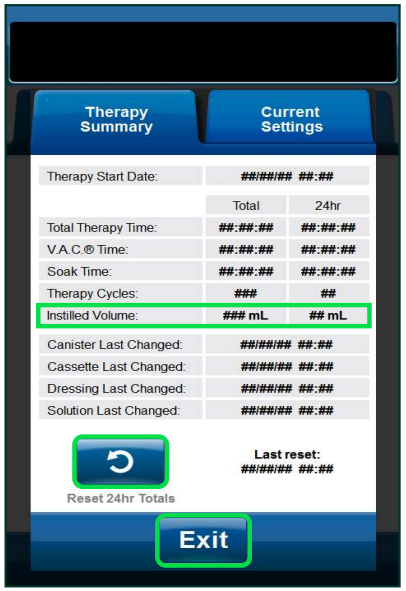
Solventum™ V.A.C.® Ulta™ Therapy Unit: Information screens—Solventum™ Veraflo™ Therapy

Select "*i*" Button from the Home screen to continue to the Therapy Summary Tab.

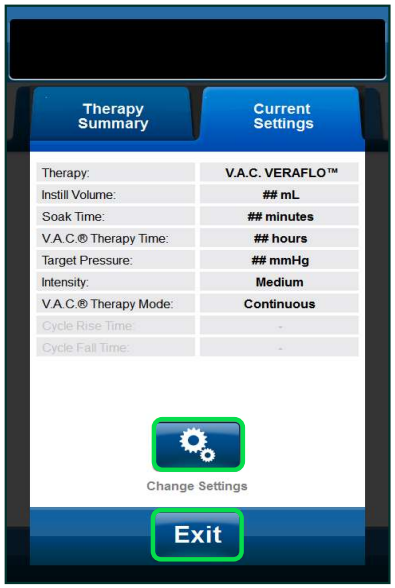
Blue arrow indicates rise or fall of Solventum™ Dynamic Pressure Control™ Therapy.



Use the Therapy Summary Tab to review a cumulative summary of therapy provided.

Select ***Exit*** to return to the Home screen for Veraflo Therapy.

Select ***Reset 24hr Totals Button*** to begin a new 24-hour log.



Use Current Settings tab to review the current therapy settings.

Select ***Change Settings*** to continue to the Confirm Settings screen.

Select ***Exit*** to return to the Home screen for Veraflo Therapy.

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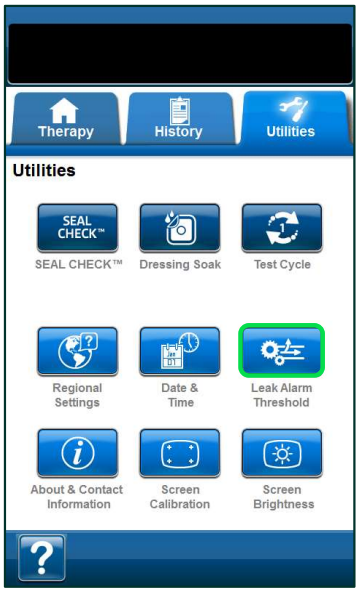
Solventum™ V.A.C.® Ulta™ Therapy Unit: Leak Alarm Threshold



Select the Utilities Tab and then press the Leak Alarm Threshold Button.

Select either Low or High Leak Alarm Threshold for both Solventum™ V.A.C.® Therapy and Solventum™ Veraflo™ Therapy.

Default Settings:

- V.A.C.® Therapy - High
- Veraflo Therapy - Low

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Solventum™ V.A.C.® Ulta™ Therapy Unit: On-device animation help

Embedded animations and alarm management features help enable self-managed troubleshooting.

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Solventum™ V.A.C.® Ulta™ Therapy Unit: Instill phase postpone

1

Pressing the button allows the user to postpone instillation at any time.

Postpone instill phase

2

Easily use the plus or minus button to select the amount of time to postpone instillation phase (2, 12, 24, 48 hrs).

3

Solventum™ Veraflo™ Therapy will automatically resume once the selected duration has elapsed.

Solventum™ V.A.C.® Ulta™ Therapy Unit: Extended delay of Therapy Inactive Alarm

Embedded animations and alarm management features help enable self-managed troubleshooting.

Therapy Inactive Extension

1. Select **Dressing Soak** while therapy is idle
2. Confirm **Dressing Soak** parameters
3. Set **Therapy Inactive** delay (30, 45, 60 minutes)
4. Restart therapy when ready

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Solventum™ Veraflo™ Therapy

Dressing options

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Solventum™ Veraflo™ Therapy dressings

Solventum™ Veraflo™ Dressing and Solventum™ Veraflo Cleanse™ Dressing

Veraflo Dressing

Veraflo Cleanse Dressing

Solventum™ Veraflo Cleanse Choice™ Dressing

Medium size

Large size

3M™ Veraflo™ Cleanse Choice Complete™ Dressings

Medium size

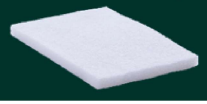
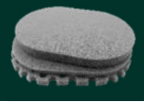
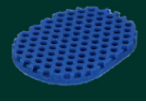
Large size

As compared to Solventum™ V.A.C.® Granufoam™ Dressings, all of the Veraflo Dressings are designed specifically for Veraflo Therapy with:

- Higher tensile strength help to ensure complete removal of foam from the wound bed[1]
- Less hydrophobic properties to help with the even distribution of topical wound solutions across the wound bed[1]

Reference: 1. Lessing C, Slack P, Hong KZ, Kilpadi D, McNulty A. Negative Pressure Wound Therapy With Controlled Saline Instillation (NPWTi): Dressing Properties and Granulation Response In Vivo. Wounds. 2011 Oct;23(10):309-19. PMID: 25881108.

Foam dressings

Dressing property	Solventum™ V.A.C.® Granufoam™ Dressing 	Solventum™ V.A.C.® White Foam Dressing 	Solventum™ Veraflo™ Dressing 	Solventum™ Veraflo Cleanse™ Dressing 	Solventum™ Veraflo™ Cleanse Choice™ Dressing 	3M™ Veraflo™ Cleanse Choice Complete™ Dressing 
Material	Black Polyurethane ether	White Polyvinyl alcohol	Black Polyurethane ether	Grey Polyurethane ether	Grey Polyurethane ether	Blue Polyurethane ether
Open cell reticulated	Yes	No	Yes	Yes	Yes	Yes
Pore size	400-600 microns all directions	60-270 microns	400-600 microns	133-600 microns depends on direction	133-600 microns	133-600 microns
Relative hydrophobicity (lowest value = highest level of hydrophobicity)	1	4	2	3	3	3
Shape	Variable shapes/sizes	Sheets	Variable shapes/sizes	Rod with center perforations for ease of separation into halves	Block foam pre-slit into three layers	Block foam with two layers combined
Tensile strength—dry	Baseline	3 times greater than baseline	1.7 times greater than baseline	2.5 times greater than Veraflo Dressing dry	2.5 times greater than Veraflo Dressing dry	2.5 times greater than Veraflo Dressing dry
Tensile strength—wet	Baseline	3.7 times greater than baseline	1.5 times greater than baseline	3 times greater than Veraflo Dressing wet	3 times greater than Veraflo Dressing wet	3 times greater than Veraflo Dressing wet

Packaging: Trays

Contents	Medium	Large
Foam, 3M™ Veraflo™ Cleanse Choice Complete™ Dressing, 2-sided foam	1	1
Ruler, Solventum™ V.A.C.® Ruler with Foam QTY Label	1	1
Solventum™ Dermatac™ Drape	2	2
Solventum™ VeraT.R.A.C.™ Pad	1	
Solventum™ VeraT.R.A.C. Duo™ Tube Set		1

Dimensions of tray: 305 mm x 234 mm x 57 mm

Shelf life: 2 years

Thank you

Note: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

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