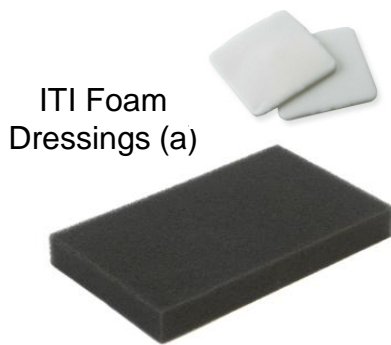


SVEDMAN® & SVED® Wound Treatment Systems

INSTRUCTIONS FOR USE

SVEDMAN® And SVED® System Components



ITI Foam Dressings (a)



Fluid Collection Canisters (b)



Therapy Units (c)



SpeedConnect™ Tubing Set with Connector & Clamp (d)



ITI Semi-permeable Drape with adhesive (f)



ITI Irrigation Tubing Set (g) & Tubing Cap (e)

Dressing Application Instructions

1. Cut the ITI Foam Dressing (a) to a size that is appropriate for the wound.
2. Place the ITI Foam Dressing (a) in the wound site taking care to avoid contact with the periwound tissue.

WARNING: Do not pack the ITI Foam Dressings into any areas of the wound. Forcing dressings in a compressed manner into any wound is contrary to approved protocols.

3. Size and trim the ITI Semi-permeable Drape (f) to cover dressing plus a 3-5 cm border of intact skin. (Save the extra drape for later use, if needed).

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INSTRUCTIONS FOR USE

Dressing Application Instructions (cont'd.)

4. Pat drape material (f) down around the wound site and over the ITI Foam Dressing (a) to ensure dressing is properly sealed.
5. Cut two 1.5 cm diameter holes in the top of the drape at both ends of the dressing. Try to locate these holes as far apart as possible (see Fig. 1).
6. Peel the backing from the SpeedConnect™ tubing flange (d) and place it above one of the holes made in Step 5. Using the tips of the fingers, press around the top of the SpeedConnect™ flange to ensure a good seal to the dressing (see Fig. 2).
7. Repeat Step 6 for the ITI Irrigation tubing flange (g) (see Fig. 3).

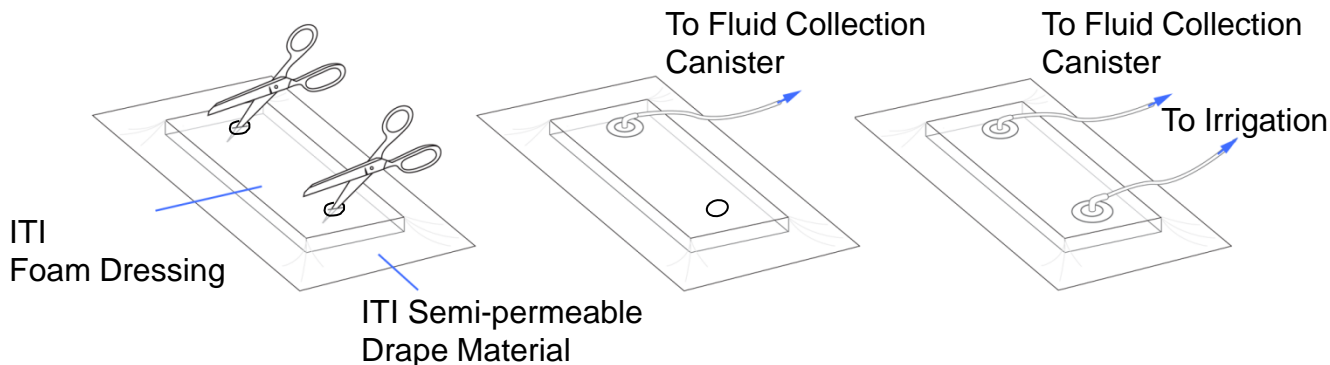


Fig. 1

Fig. 2

Fig. 3

8. Connect the ITI Irrigation tube (g) to any standard I.V. giving set or infusion pump. **NOTE: The solution to be used for wound irrigation should be appropriate for topical applications** (see SVEDMAN® or SVED® Wound Treatment System Indications and Precautions for more information on the suggested types of aqueous wound therapy solutions). Make sure that the irrigation fluid supply remains off until therapy is started (See Therapy Unit Instructions).
9. When Irrigation is discontinued, for example while changing the fluid reservoir, attach the Tubing Cap (e) to the ITI Irrigation tube (g) to prevent leaking.
10. Proceed to the therapy unit Instructions to apply negative pressure wound therapy with irrigation.

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Therapy Unit Instructions

1. Ensure that an ITI Fluid Collection Canister (b) is properly placed in the receptacle of the Therapy Unit (c) **Note: Always use a new canister with a new patient.**
2. Inspect the adhesive tubing flanges to ensure that they are properly connected to the ITI Foam Dressing (a) and that the connections are well sealed.
3. Connect the distal end of the SpeedConnect™ tubing (d) with the blue tapered connector to the suction port of the Canister (b). Gently twist and push the connector on just enough to secure and seal it. Also, make sure that the clamp on the SpeedConnect™ tube (d) is open.
4. If utilizing the SVEDMAN® therapy unit –
 - Insert the “Suction” tube from the Canister (b) to the “SUCTION” connector on the top-front of the Therapy Unit (c).
 - Insert the “Sensing” tube from the Canister (b) to the “SENSING” connector on the top-front of the Therapy Unit (c). The metal tabs on the connectors may need to be depressed to permit tube insertion.

If utilizing the SVED® therapy unit, slide canister into holder and press upwards until the canister locks into place.

5. Plug the Therapy Unit's A.C. Adapter into a suitable 120 VAC, 60 Hz, outlet. Insert the power plug into the Power Jack on the side of the Therapy Unit.
6. Press the ON (1) button to begin therapy. Check to verify the green button light is illuminated. Adjust the desired therapy level by pressing the appropriate pressure button (-70 mmHg, -120 mmHg or -150 mmHg). Software versions 2.57 and higher can operate in an intermittent suction mode with a 5 minute “on” and 2 minute “off” cycle. To turn the intermittent mode on, press and hold the desired setting button then momentarily press the OFF (0) button. The unit will beep “•—•—” and the green ON (1) button will begin flashing indicating the unit is now operating in intermittent mode. Release both buttons. To turn the intermittent mode off (and return the device to the default continuous mode), repeat the above steps. The unit will produce a single long beep and the green ON (1) button will steadily illuminate. The unit will remember the mode setting when the power is turned OFF and ON. During intermittent operation, the unit will provide target therapy pressure throughout the “on” part of the cycle and approximately -25 mmHg throughout the “off” part of the cycle. By maintaining this lower pressure while the unit is off, the dressing seal is never compromised. This method of applying intermittent pressure also increases patient comfort.
7. Dressing should collapse, indicating the presence of vacuum. Once dressing integrity is verified, turn the irrigation fluid supply on and adjust flow rate for desired therapy.
8. Carefully check dressing for vacuum or fluid leaks and repair with additional ITI Semi-permeable Drape (f) material as needed.
9. The therapy unit (c) should be operated at least 22 out of every 24 hours to prevent possible infection.

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INSTRUCTIONS FOR USE

Therapy Unit Instructions (cont'd.)

Alarm Troubleshooting

1. If the “Low Pressure/Leak” LED light illuminates and an audible alarm sounds, check the dressing and tubing for leaks. Correct as necessary and press the OFF (0) and ON (1) buttons to reset the alarm.
2. If the “Canister Full” LED light illuminates and an audible alarm sounds, remove the Fluid Collection Canister (b), and replace with a new canister. Press the OFF (0) and ON (1) buttons to reset the alarm.
3. To remove the Canister (b), depress the metal tab on the connector with one hand while gently pulling with the other hand.

BATTERY OPERATION

NOTE: *The SVEDMAN® and SVED® Wound Treatment Systems are designed to permit patient use of the product while the internal battery is charging. The therapy unit will continue to operate properly while charging is taking place.*

Average Battery Life

The specified battery life of the SVEDMAN® and SVED® Wound Treatment Unit with a fully-charged battery is up to 18 hours. The actual life is dependant on the integrity of the dressing. A leak in the dressing can significantly reduce overall battery longevity.

Average Time for Recharging

To ensure the battery has been fully charged, the unit should be connected to an A.C. supply for approximately 3 hours. After approximately 2 hours of charging, the unit will have achieved 80% of total battery capacity.

Low Battery Alarm

While running on battery, a low-battery alarm will “chirp” every 10 seconds and the OFF button will begin flashing when remaining capacity of the battery is less than 20%. Typically, the unit will continue to operate for approximately 30 minutes to 1 hour after the low-battery alarm is activated.

Low Battery Shutoff

If the battery charge falls below a critical level, the unit will shutoff automatically and therapy will be discontinued. At this point, the unit must be plugged into an A.C. power source for therapy to resume. Once the A.C. Adapter is plugged in, pressing the ON button will restart the unit at its previous settings.

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INSTRUCTIONS FOR USE

Therapy Unit Instructions (cont'd.)

Recharging the Battery

Plug the power cord from the A.C. Adapter into the power receptacle on the side of the therapy unit. Plug the A.C. Adapter into a suitable 120 VAC, 60 Hz wall outlet.

When the unit is connected to an AC power source, the GREEN LED above the power receptacle will illuminate indicating AC power is present and the AMBER LED will illuminate when the battery is charging.

Once the battery is fully charged, the AMBER LED will extinguish indicating the charge cycle is complete.

When the Therapy Unit is disconnected from the AC power source, the device will automatically switch over to the internal battery and continue to operate without interruption.

Therapy Selection Lock/Unlock

The SVEDMAN® and SVED® Wound Treatment Units are equipped with a therapy locking feature designed to prevent unauthorized individuals from changing the therapeutic settings inadvertently.

Locking

To lock the unit, press and hold the desired therapy level (-70, -120, -150 mmHg) for three seconds until three audible beeps are heard. At this point, the unit is locked. Pressing any other therapy level will result in three beeps with no change in setting. This therapeutic setting will be recalled each time the unit is powered OFF and ON, and the unit will remain locked until it is subsequently unlocked by the caregiver.

Unlocking

To unlock the unit, press and hold the selected therapy button (the lit button) until three audible beeps are heard. At this point the unit is unlocked and therapy settings can be changed. Additionally, when the unit is powered OFF and ON, the unit will remain unlocked and will automatically revert to the default setting of -120 mmHg.

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INDICATIONS

The SVEDMAN® and SVED® Wound Treatment Systems are indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

Types of wounds for which the SVEDMAN® and SVED® Wound Treatment Systems have been indicated include chronic, acute, traumatic, subacute, and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts.

CONTRAINDICATIONS

The SVEDMAN® and SVED® Wound Treatment Systems are contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulas, or necrotic tissue with eschar present. Do not place the ITI Foam Dressing over exposed blood vessels or organs. The ITI Foam Dressings are also contraindicated for hydrogen peroxide and solutions which are alcohol based or contain alcohol. It is not recommended to deliver fluids to the thoracic cavity.

PRECAUTIONS

Precautions should be taken for patients with active bleeding, difficult wound hemostasis, or who are on anticoagulants. When placing the ITI Foam Dressing in close proximity to blood vessels or organs, take care to ensure that they are adequately protected with overlying fascia, tissue or other protective barriers. Exposed tendon, nerves or blood vessels should be protected by moving available muscle or fascia over them or by a layer of synthetic material. Greater care should be taken with respect to weakened, irradiated or sutured blood vessels or organs. Bone fragments or sharp edges could puncture a dressing barrier, vessel or organ. Wounds with enteric fistula require special precautions in order to optimize therapy.

ADDITIONAL PRECAUTIONS

- Defibrillation:** Remove the entire ITI Foam Dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit electrical current transmission and/or patient resuscitation.
- Magnetic Resonance Imaging (MRI):** The SVEDMAN® and SVED® Wound Treatment Unit is not MRI-compatible. Do not take into the MRI area.
- Large Canisters:** Use of Large Canisters (>500ml) may increase serious risks associated with excessive fluid loss. Monitor patient status continually. **DO NOT USE** for infants or other patients with low fluid volume, nor for patients at high risk of major hemorrhage.
- Hyperbaric Oxygen Therapy (HBO):** **NEVER allow a device – whether on or off – inside a hyperbaric chamber.** The device must be disconnected from the patient prior to HBO treatment. Refer to the Clinical Guidance for the Innovative Therapies Wound Treatment Systems for more information on use with HBO therapy.

SVEDMAN® & SVED® Wound Treatment Systems

INSTRUCTIONS FOR USE

ADDITIONAL PRECAUTIONS (cont'd.)

- The SVEDMAN® and SVED® Wound Treatment Systems are intended for use with saline solutions in a physiologic pH range that can optionally include topical wound treatment solutions.
- Various topical agents, such as hydrogen peroxide, are not intended for extended tissue contact. If in doubt about the appropriateness of using a solution with the SVEDMAN® or SVED® Wound Treatment Systems, contact the solution's manufacturer.
- Do not apply solutions in conflict with the manufacturer's instructions for use.
- During irrigation therapy, the ITI Foam Dressing is a closed system and is NOT vented to atmosphere.
- Do not use where temperature of fluid could cause an adverse reaction, such as a change in patient's core body temperature.
- During Wound Irrigation Therapy, the IV bag should be checked periodically to ensure proper fluid delivery. In addition, when a canister fills with fluid, it should be replaced or emptied immediately as irrigation fluid and wound exudate will not be removed from the dressing once the canister is full.

KEEP THERAPY ON

The SVEDMAN® and SVED® Wound Treatment Systems should be operated at least 22 hours out of every 24 hour period. Remove the ITI Foam Dressing if irrigation therapy is terminated or is off for more than 2 hours in a 24 hour period.

DRESSING CHANGES

Clean the wound per physician order prior to dressing application. Routine dressing changes should occur every 48 to 72 hours. Dressing changes for infected wounds should be accomplished more frequently than 48-72 hours. Always replace with sterile disposables from unopened packages. NOTE: *Follow established institution protocols regarding clean versus sterile technique.*

MONITORING THE WOUND

Inspect the dressing frequently to ensure foam is collapsed and irrigation therapy is being delivered in a consistent manner. Monitor periwound tissue and exudate for signs of infection or other complications.* Extra care and attention should be given if there are any signs of possible infection or related complications. Infection can be serious. With or without the SVEDMAN® or SVED® Wound Treatment System, infection can lead to many adverse complications including pain, discomfort, fever, gangrene, toxic shock, septic shock, and various other complications. With signs of more serious complications of infection, discontinue use of the SVEDMAN® or SVED® Wound Treatment System until the serious infection is diagnosed and properly treated.

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INSTRUCTIONS FOR USE

DISCOMFORT / ADHERENCE

If patient complains of discomfort during dressing change, consider pre-medication, use of a non-adherent prior to foam placement or irrigation of a topical anesthetic agent such as 1% Lidocaine prior to dressing removal.

UNSTABLE STRUCTURES

Over unstable body structures such as unstable chest wall or non-intact fascia, use the lowest pressure setting on the SVEDMAN® or SVED® Wound Treatment Unit.

SPINAL CORD INJURY

In the event a patient experiences autonomic hyperreflexia (sudden elevation in blood pressure or heart rate in response to stimulation of the sympathetic nervous system) discontinue use of the SVEDMAN® or SVED® Wound Treatment System to help minimize sensory stimulation.

BODY CAVITY WOUNDS

Underlying structures must be covered by natural tissues or synthetic materials that form a complete barrier between the underlying structures and the ITI Foam Dressing.

ITI FOAM DRESSING USE

The ITI Foam Dressing sets distributed by Innovative Therapies, Inc. are packaged sterile and are to be used exclusively with the SVEDMAN® and SVED® Wound Treatment Systems. The decision to use clean versus sterile/aseptic technique is dependent upon wound pathophysiology and physician/clinician preference. All components of the SVEDMAN® and SVED® Wound Treatment Systems disposable sets are latex free.

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*Signs of possible infection may include fever, tenderness, redness, swelling, itching, rash, increased warmth in the wound area, purulent discharge or a strong odor. Nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucous membrane, disorientation, high fever (>102°F, 38.8°C), refractory hypotension, orthostatic hypotension, or erythroderma (a sunburn-like rash) may be added signs of more serious complications of infection.

NOTE: All disposable components of the SVEDMAN® and SVED® Wound Treatment Systems are FOR SINGLE USE ONLY. The single use components must not be re-used with another patient. Hazards associated with reuse of single use components can be found at www.itimedical.com.

Be sure to comply with all other **CONTRAINDICATIONS** and **PRECAUTIONS** for the SVEDMAN® and SVED® Wound Treatment Systems.



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