CardinalHealth
Essential to care™

Cardinal Health™
Negative Pressure Wound Therapy SVED®

Clinician User Manual

CAUTION: This SVED® Clinician User Manual is not a guarantee or warranty. It is intended only as an operational guide. For additional information and questions, please contact the Cardinal Health Customer Service department at 1.866.484.6798.

In order for the SVED® to provide safe, reliable, and proper performance, the following conditions must be met. Failure to comply with these conditions will void all pertinent warranties.

- There are no user serviceable components in the SVED®. All assembly, modification, maintenance, and/or repair must be carried out only by qualified personnel authorized by Cardinal Health. Unauthorized modification of the SVED® may result in physical hazards, including delayed therapy, electrocution and fire that may lead to injury or death.
- The electrical installation of the room in which the SVED® is used complies with the appropriate national electrical standards.
- The SVED® must be used in accordance with this Clinician User Manual and all associated labeling and the Instructions for Use.
- Any SVED® that does not function as expected must be returned to Cardinal Health.

CAUTION: Federal law restricts this device to sale by, or on the order of, a physician. As with any prescription medical device, failure to follow product instructions or changing settings and performing therapy applications without the express direction and/or supervision of a trained clinical caregiver may lead to improper product performance and the potential for serious or fatal injury.

Safety and Warnings

***Note to healthcare personnel providing training to lay users or caregivers (lay responsible organizations)*:**
Be sure to include all of the warnings below when providing training to lay users, especially in a home care environment. Lay users and caregivers should contact Customer Support if there is a change in the performance of the SVED®. Additionally, lay users should be instructed on proper cleaning procedures to avoid hazards such as electric shock. Lay users and caregivers should also be trained on inappropriate environments for use (e.g. bathtub). For guidance on training, please contact Customer Support.

WARNING: Strangulation hazard. Do not leave A.C. Power Adapter cord, tubing or other choking hazards where infants or young children can become caught. If these objects get wrapped around the neck, strangulation and death can occur.

WARNING: Choking hazard. The SVED® contains small parts, which could become detached and pose a choking hazard. Some of these components could be inhaled or swallowed by a small child, toddler or infant, which could result in suffocation or death. Keep all parts of the SVED® system out of reach of small children.

WARNING: Do not modify this equipment without authorization from the manufacturer. Modification of this system could result in physical hazards, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

WARNING: Use only the Cardinal Health™ NPWT Dressings and accessories listed in this manual. Use of other dressings and accessories can create hazardous situations, including improper therapy or delayed therapy. This could result in improper healing, damage to the wound area and infection.

CAUTION: Use the SVED® system only as described in this user manual. Do not interconnect the SVED® with other devices not included in this user manual. Failure to comply could result in improper therapy and could result in damage to the SVED®.

CAUTION: This system is not intended to be used in MRI environments or in the presence of strong magnetic fields. Do not use this device in any areas with strong magnetic fields. The system contains metal components which could cause unintended movement. This unintended movement could cause clinician or patient harm due to falling objects or collisions.

CAUTION: If you are in an environment with pet hair, please use caution when adhering the wound dressing to the wound site. Pet hair could contaminate the wound site and prevent adhesion of the wound dressing. This could result in possible infection of the wound or reduced effectiveness of the system.

CAUTION: The SVED® system can be used outdoors for short periods of time (not more than 24 hours). Shelter from rain.

Table of Contents

1. Introduction

The SVED® Negative Pressure Wound Therapy (NPWT) system is comprised of the SVED®, the NPWT Dressing Kit, the NPWT Canister and the A.C. Power Adapter. In order to assure the highest safety, quality and efficacy, the SVED® should only be used with the Cardinal Health™ NPWT Dressing Kits and Cardinal Health™ NPWT disposables. Use of any other brand of wound dressings are not compatible with the SVED® and are not recommended.

1.1 Indications

The SVED® system is an integrated wound management system, indicated for the application of continual or intermittent negative pressure wound therapy as the SVED® may promote wound healing by the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials.
The SVED® system is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The SVED® system is intended for use in acute, extended and home care settings.

1.2 Contraindications

The SVED® is 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 Cardinal Health™ NPWT Dressing over exposed blood vessels or organs. The Cardinal Health™ NPWT 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.

1.3 Precautions

Precautions should be taken for patients with infected wounds, active bleeding, difficult wound hemostasis, or who are on anticoagulants. When placing the Cardinal Health™ NPWT 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.

- **Defibrillation:** The dressings must be removed 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 SVED® is not MRI-compatible and cannot be used in the presence of strong magnetic fields. Do not take the SVED® into the MRI area or any area of high magnetic fields. The SVED® contains metal components that could cause unintended movement resulting in harm due to falling objects or collisions.
- **Hyperbaric Oxygen Therapy (HBO):** Do not take the SVED® — whether on or off — inside a hyperbaric chamber. Clamp the tubing and disconnect the SVED® prior to HBO treatment.
- **DO NOT USE** for infants, pediatric patients, any other patients with low fluid volume, or for patients at high risk for major hemorrhage.
- During negative pressure wound therapy, the SVED® and dressings are a closed system and are NOT vented to atmosphere.
- When the NPWT Canister is full, replace immediately. Wound exudate is not removed from dressing if the canister is full. See **3.3 Removing the NPWT Canister** and **3.2 Inserting the NPWT Canister**.

1.4 Safety Tips

Keep Therapy On

The SVED® should be operated at least 22 hours out of every 24-hour period. Remove the Cardinal Health™ NPWT Dressing if 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 at least every 48 to 72 hours. Dressing changes for infected wounds should be accomplished more frequently than 48 to 72 hours. Follow established facility protocols regarding clean versus sterile technique.

Monitoring the Wound
Inspect the dressing frequently to ensure that the dressing is collapsed and that negative pressure wound therapy is being consistently delivered. Monitor wound exudates for signs of active bleeding. Monitor peri-wound tissue and exudate for signs of infection or other complications.

Signs of possible infection may include fever, tenderness, redness, swelling, itching, and rash, increased warmth in the wound area, sudden increase in pain, purulent discharge or a strong odor. Nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucous membrane, disorientation, high fever, refractory hypotension, orthostatic hypotension or peri-wound induration (redness and increased skin temperature around wound) may be added signs of more serious complications of infection. If any sign of infection is noted, discontinue the use of the SVED® until the infection is diagnosed and properly treated.

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

Unstable Structures
Use the lowest Pressure Setting on SVED® over unstable body structures such as unstable chest wall or non-intact fascia.

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 therapy to help minimize sensory stimulation.

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

NOTE: All dressing components of the Cardinal Health™ NPWT Dressing Kit are packaged sterile. The decision to use clean versus sterile/aseptic technique is dependent upon wound pathophysiology and physician/clinician preference. All components of the NPWT Dressing Kits are made without natural rubber latex.

Be sure to comply with **1.2 Contraindications** and **1.3 Precautions**.

CAUTION: Do not pack the NPWT dressings into any areas of the wound. Forcing dressings into any wound may compromise negative pressure wound therapy and wound healing.

1.5 Features

Simple Operation: Negative pressure wound therapy activation and changing of Pressure Settings can be accomplished with the push of a button. Pressure Settings can be quickly changed by pressing one of three buttons. Pressure Settings can be locked by the clinical caregiver (**4.4 Negative Pressure Wound Therapy Lock/Unlock**). Lights next to the Pressure Settings clearly indicate current therapeutic settings.

Light Weight/Impact Resistant: The therapy device weighs .9kg (2.0 lb.) for increased mobility. The cover of the SVED® is impact resistant to help prevent damage from dropping.

Noise: The SVED® is quiet in its normal operation with a well-sealed dressing.

Battery: An internal battery in the SVED® provides up to 18 hours of operation from a single full charge. The battery charges while the SVED® is plugged into an outlet with the A.C. Power Adapter. If the battery charge is less than 20 percent, the SVED® "chirps" and the OFF Button flashes.

Power/Charging Status: Indicates the SVED® is charging the internal battery.

Intermittent Mode: The SVED® can be set to operate intermittently (5-minute on/2-minute off cycle). The SVED® maintains pressure at -25mmHg during 2-minute "off" cycle to prevent loss of dressing seal.

Alert Display: Automated alerts for Low Pressure/Leak and Canister Full/Blockage. Alerts are both visual and audible. Alerts self-reset once the problem is corrected or can be manually reset by turning the SVED® off and then back on.

IV Pole Adapter: Pole clamp permits the SVED® to be mounted to a wide range of standard IV poles: 2.2 to 5.0cm (0.9 to 2.0 in.) in diameter.

Tubing with SpeedConnect™: 8-foot, dual-lumen tubing set with adhesive SpeedConnect™ makes connection to the dressing easy.

Canisters: 300cc and 500cc canisters with gel solidifiers are available. Both canisters can be used for normal and highly exudating wounds.

CAUTION: Monitor patient status continually. DO NOT USE for infants, pediatrics, or other patients that have low fluid volume, or for patients at high risk of hemorrhage.

2. Care & Cleaning

Carefully read **1.3 Precautions** and **1.4 Safety Tips** before cleaning the SVED®.

Standard Precautions should be used to minimize the risk of infection and contact with contaminated blood or bodily fluids during the dressing changes and cleaning of the SVED®. It is important to protect all exposed skin and mucous membranes by using Personal Protective Equipment (PPE). PPE includes:

- Disposable gloves
- Protective eyewear
- Protective mask
- Disposable impervious gown

2.1 Cleaning

Perform a visual inspection of the SVED®. Check for any sign of contamination or fluid going into the canister ports. Ensure that the SVED® is functioning properly. If the SVED® is not operating properly, refer to **4.9 Troubleshooting** or contact Cardinal Health at 1.866.484.6798.

To help reduce the risk of infection and contact with contaminated blood and bodily fluids, it is recommended to wear personal protective equipment (PPE) when cleaning the SVED®.

NOTE: Always follow Standard Precautions. Follow facility protocols regarding clean versus sterile technique.

NOTE: Cleaning of the SVED® must not be performed when the SVED® is connected to a patient or power source. Disconnect the SVED® from the patient and power source before cleaning.

The following cleaning procedure must be performed at least once a week and must be performed between patients. Wipe the SVED® with a diluted solution of 5 milliliters bleach in 1 liter of warm water (approximately 1 teaspoon bleach in 1 quart water). Use a coarse cloth and wring out any excess solution until the cloth is damp and not dripping. Bleach based disinfecting wipes for cleaning medical equipment may also be used.

1. Clean all surfaces of the SVED®, including the ports and the A.C. Power Adapter, then allow the solution to air dry on the SVED®.
2. If there is visible soilage on the SVED®, clean it a second time after the first cleaning has removed the soilage.
3. Wipe down the SVED® with a clean, dry cloth to remove any bleach residue.
4. Visually inspect the SVED® and A.C. Power Adapter for damage. If damage is noted, take the SVED® or the A.C. Power Adapter out of service and replace per protocol.

CAUTION: Particular care must be taken when handling undiluted germicide concentrate or chlorine bleach, including proper shielding of eyes. Always mix by adding concentrated germicide or chlorine bleach to the water. NEVER intermix germicides or mix germicides with chlorine bleach. Do not spray liquids directly on to the SVED®.

CAUTION: Avoid spilling liquid on any part of the SVED®. Spilling liquid on the SVED® may cause the SVED® to operate erratically, possibly causing a potential hazard to the patient or clinical caregiver.

Carrying Case and IV Pole Adapter

Follow the same procedure as above.

2.1 A.C. Power Adapter Inspection

The A.C. Power Adapter should be inspected regularly for damage and/or unusual wear. Replace damaged or worn A.C. Power Adapter immediately. Replacement A.C. Power Adapters are available from Cardinal Health.

WARNING: The SVED® must be used with the supplied A.C. Power Adapter. Use of another adapter/power cord could result in physical hazards, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

3. Patient Care

It is recommended that all sections of this manual be reviewed prior to using the product. Carefully read the **1.1 Indications**, **1.2 Contraindications**, **1.3 Precautions** and **1.4 Safety Tips** before using the SVED® for patient care.

3.1 Applying the NPWT Dressing

1. Cleanse wound according to facility protocols or physician order.
2. Debride all necrotic tissue including eschar and slough.
3. Be certain the wound has achieved hemostasis.
4. Visually examine and palpate wound bed to locate any blood vessels or delicate underlying structure in close proximity.
5. Prepare area around wound to permit adhesion of the polyurethane drape.

NOTE: If peri-wound area is excessively moist or oily, a medical-grade liquid adhesive may improve sealing. For fragile skin, use a skin sealant prior to drape application, or frame the wound with a skin barrier layer, such as a hydrocolloid, the Cardinal Health™ Drape or Cardinal Health™ SensiSkin™ Drape.

6. Take measurements of the wound dimensions and note wound type. Select the appropriate dressing size based on wound assessment. Open the sterile kit to expose the black foam, the tubing with SpeedConnect™ and the drape. Set aside the tubing with SpeedConnect™ and drape from the NPWT Dressing Kit.
7. Cut the black foam to a size that is appropriate for the wound (**Figure 1**). Document the number of black foam pieces used to fill the wound in the patient's chart.

CAUTION: Do not cut the black foam over or around the wound to avoid debris from the black foam dressing from falling into the wound (**Figure 2**).

8. Place the black foam dressing in the wound taking care to avoid contact with the peri-wound skin (**Figure 3**). Black foam should be higher than skin level and cover the entire wound base. Black foam may be stacked for deep wounds.

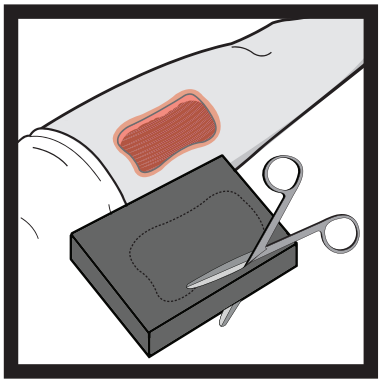


Figure 1

Figure 2

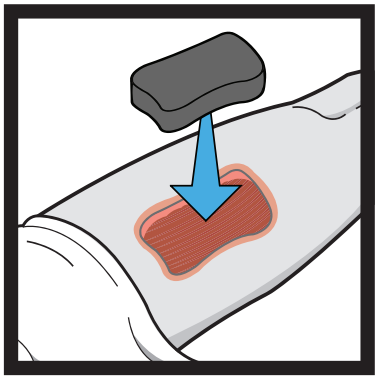


Figure 3

CAUTION: Do not pack the black foam into any areas of the wound. Forcing foam into any wound is contrary to approved protocols. Loosely fill all visible dead space in the wound. Do not thin black foam, as thinning may cause over collapse of the dressing and prevent fluid from moving away from wound base.

Use of White Foam

Per clinician's discretion, white foam may be used in wounds needing extra protection, such as protrusion of bone and in small tunneling and undermining. White foam should be used in an intact, single layer and covered with black foam when not used in small tunnels or in undermining. If the white foam needs to be cut to size, please note that non-linear shape cuts (e.g., curves, spirals, etc.) and straight cuts less than 3cm wide may increase the likelihood that the white foam will tear upon removal.

9. Remove the drape from the Dressing Kit. Size and trim the drape to cover the wound plus a 3-5cm border of intact skin (extra pieces of drape can be used to seal dressing leaks if needed). Always keep one side of the drape intact for ease of dressing application. (**Figure 4**).

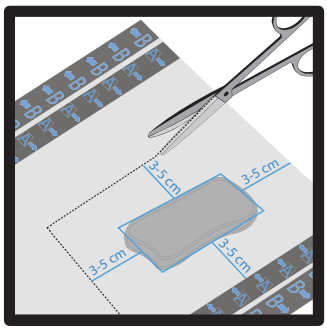
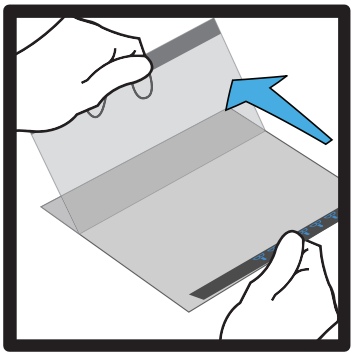


Figure 4

10. Remove the drape's release liner starting with tab A (**Figure 5**). Invert and place over the foam and peri-wound (**Figure 6**) and continue removing the contact layer with tabs B and C (**Figures 7-8**). Remove the remaining perforated tab (**Figure 9**). Gently press drape material down around the wound site and over the foam to ensure dressing is properly sealed.



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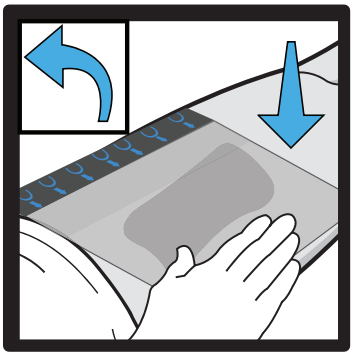

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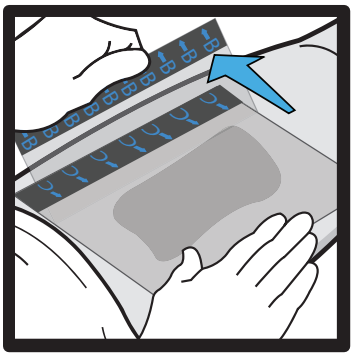

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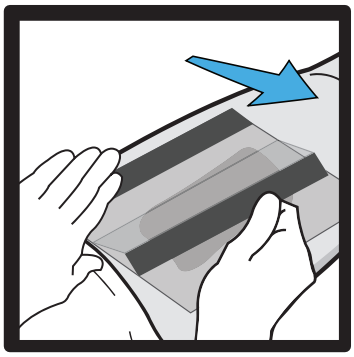

Figure 8

Figure 9

11. Cut a 1cm diameter hole in the top of the drape at a convenient location over the foam dressing by pinching and lifting the drape (Figure 10).

12. Remove the tubing from the NPWT Dressing Kit. Locate the SpeedConnect™ and peel the backing to expose adhesive. Place it over the hole made in Step 11 (**Figures 11-12**). Using the tips of the fingers, press around the top of the SpeedConnect™ to ensure a good seal to the drape.

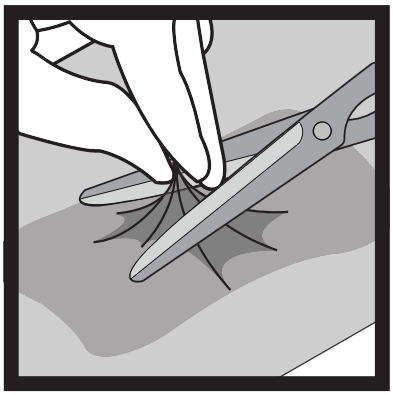

Figure 10

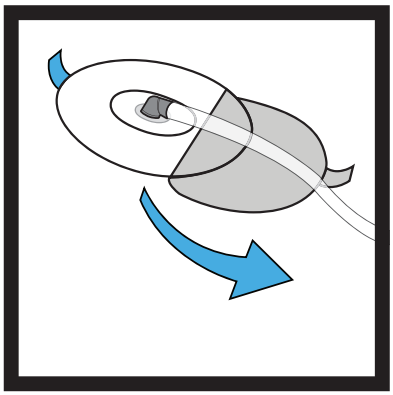

Figure 11

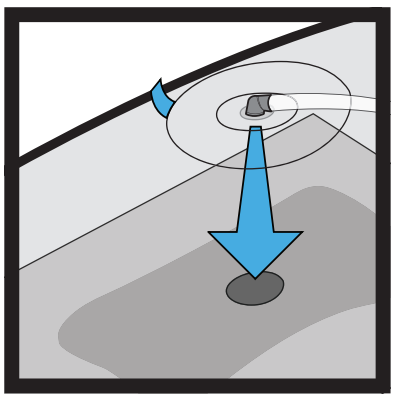

Figure 12

3.2 Inserting the NPWT Canister

1. To insert the canister, line up the two ports on the canister with the two ports on the SVED®. Press the canister up and into the SVED® until it clicks and locks into place.

NOTE: Always use a new canister with a new patient.

Figure 13

2. Connect the distal end of the SpeedConnect™ Tubing with the blue tapered connector to the patient port of the Canister (**Figure 14**). Gently twist and push the connector on just enough to secure and seal it.
3. Verify the dressing application is correct, the tubing is connected and the tubing clamp is open.
4. Begin negative pressure wound therapy (see **4. Operating Instructions**).

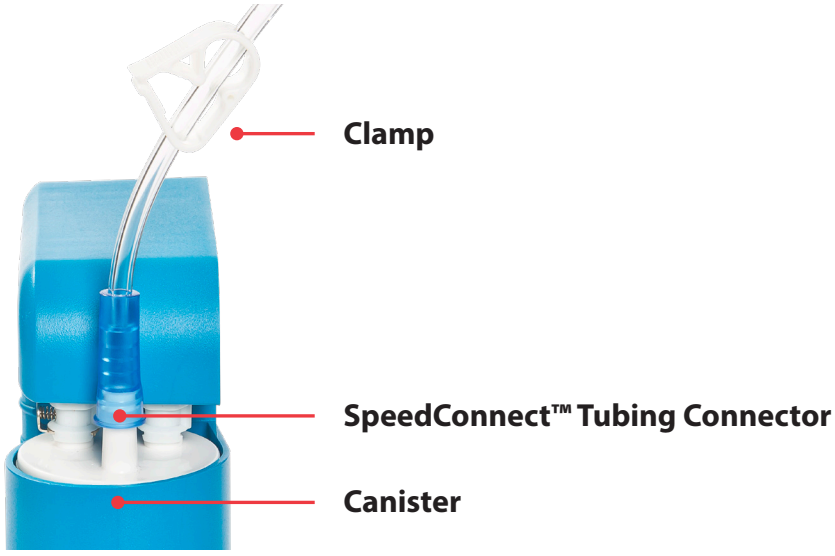

Figure 14

3.3 Removing the NPWT Canister

1. Close tubing clamp.
2. Press the off button on the SVED®.
3. Disconnect SpeedConnect™ tubing from top of canister. Twisting the tapered connector will make removing the suction tube from the canister easier.
4. Press Canister Release Button and gently pull the bottom of canister down to remove from the SVED®.
5. Cap the canister. Dispose of canister according to facility protocols as well as local, state and federal regulations.

NOTE: The canister should be replaced when full, or at least once every week, to minimize odors and the potential for contamination.

3.4 Removing the NPWT Dressing

Carefully read the **1.5 Safety Tips** before removing the dressing.

NOTE: Wounds must be carefully monitored at regular intervals. In a non-infected wound, dressings should be changed every 48 to 72 hours; as determined by the clinician. For infected wounds, dressings may need to be changed more often than 48 to 72 hours; based on clinical evaluation of the wound.

Standard Precautions should be used to minimize the risk of infection and contact with contaminated blood or bodily fluids during the dressing changes and cleaning of the SVED®. It is important to protect all exposed skin and mucous membranes by using Personal Protective Equipment (PPE). PPE includes:

- Disposable gloves
- Protective eyewear
- Protective mask
- Disposable impervious gown

1. With the SVED® ON, lift a corner of the drape to allow air to enter the system, moving any fluid in the tubing into the canister.
2. Close suction tubing clamp.
3. Press the OFF button to turn the therapy off.
4. Disconnect tubing from top of canister. Twisting the tapered connector will make removing the suction tube from the canister easier.
5. Gently stretch the drape laterally and slowly pull up and away from skin. Lateral stretching of the drape will help release the adhesive and minimize trauma to the patient's skin.

NOTE: If the patient complains of discomfort during the dressing change, consider pre-medication, use of a non-adherent wound contact layer prior to foam placement in the wound or irrigation of a topical anesthetic agent such as 1 percent lidocaine prior to dressing removal.

6. Remove foam from wound. Make sure that the number of pieces removed from the wound matches the number of pieces that were placed into the wound. If the numbers do not match, further procedures may have to be performed to resolve the difference.
7. Discard used foam, tubing, canister and drape in accordance with applicable rules, regulations and infection control protocols, and always follow Standard Precautions.

3.5 Disposal of Used Components

After patient use, all used disposable components of the system should be treated as contaminated. These may include:

- The NPWT foam dressing and polyurethane drape
- The canister
- The tubing
- Irrigation tubing set and irrigation delivery set

Dispose of all used components in accordance with facility protocols as well as local, state and federal regulations.

3.6 Delivering Simultaneous Irrigation™ Technology

Cardinal Health offers two irrigation tubing set options that deliver irrigation and negative pressure wound therapy simultaneously. The NPWT Irrigation Tubing with SpeedConnect™ consists of a single-lumen tubing with SpeedConnect™ and a luer lock connector to connect to the irrigation of choice. The NPWT Irrigation Delivery Set consists of a single-lumen tubing with SpeedConnect™ and an irrigation delivery bag that allows the irrigation of choice to be delivered through the delivery bag. Both tubing options deliver irrigation solution to the wound.

Precautions

- Simultaneous Irrigation™ Technology can be utilized with the SVED®. Appropriate solutions for Simultaneous Irrigation™ Technology may include normal saline or other solutions indicated for topical wound treatment.
- Any solution cleared for use in topical wound irrigation can be used as the wound irrigant.
- Various topical agents, such as hydrogen peroxide and solutions containing alcohol, are not intended for extended tissue contact. If in doubt about the appropriateness of using a solution with the SVED®, contact the solution's manufacturer.
- Do not apply solutions in conflict with the manufacturer's instructions for use.
- During irrigation therapy, the dressing is a closed system and is NOT vented to atmosphere.
- Do not use where temperature of fluid could cause and adverse reaction, such as a change in patient's core body temperature.
- During irrigation therapy, check the irrigation bag periodically to ensure proper fluid delivery. In addition, when a canister fills with fluid, it should be immediately replaced as irrigation fluid and wound exudate is not removed from the wound if the canister is full.

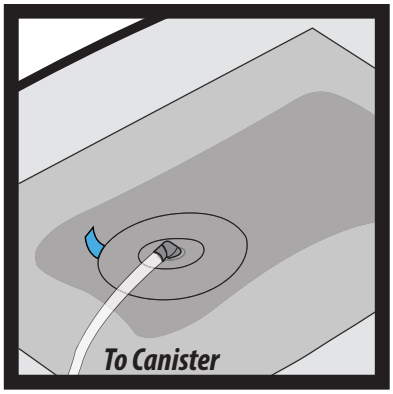

Figure 15

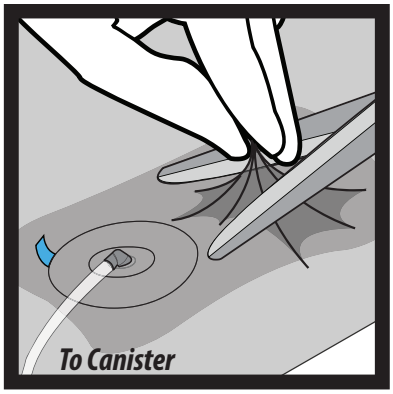

Figure 16

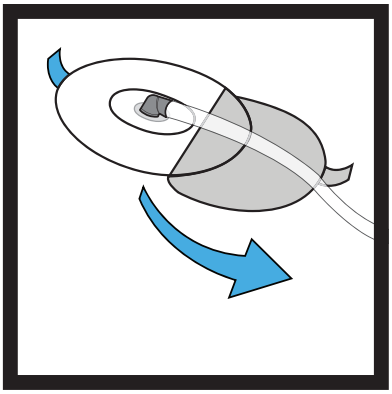

Figure 17

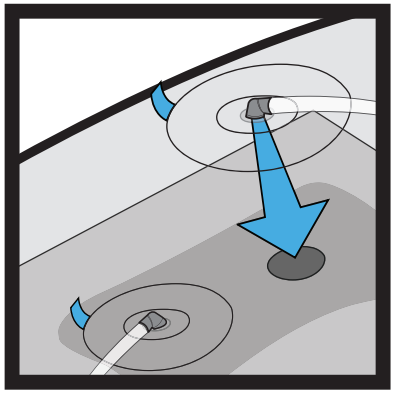

Figure 18

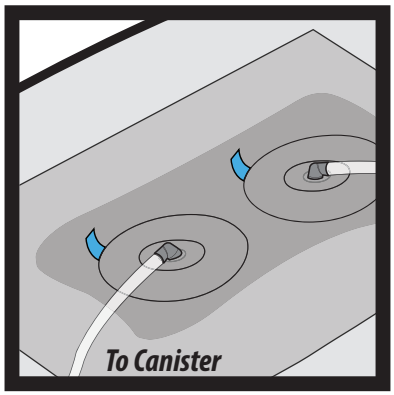

Figure 19

Instructions

1. Make sure the irrigation fluid supply remains clamped off until the therapy is started and target pressure is achieved.
2. Obtain a physician order for irrigation solution type and delivery rate.
3. Apply NPWT Dressing (see **3.1 Applying the NPWT Dressing**).
4. Connect NPWT Irrigation Tubing attachment to the irrigation solution container or use the NPWT Irrigation Delivery Set, which incorporates an irrigation bag with a tubing set together. Close the irrigation clamp completely.
5. Hang irrigation bag on IV pole higher than the wound.
6. Select desired location for Irrigation SpeedConnect™. Cut a 1cm diameter hole in the top of the drape where the Irrigation SpeedConnect™ is to be placed (**Figures 15 and 16**).
7. Peel off the SpeedConnect™ backing to expose the adhesive pad and place over hole made in Step 6 (**Figure 17**). Using the tips of the fingers, gently press around the Irrigation SpeedConnect™ to ensure a good seal to the dressing.

NOTE: The Irrigation SpeedConnect™ may be placed in close proximity to the SpeedConnect™, or in larger wounds may be placed over another area of the wound distal to the SpeedConnect™.

8. Turn on the SVED® and allow dressing to reach set pressure.
9. Open the clamp on the Irrigation tubing to allow irrigation solution to flow until the solution begins to move through the tubing and into the canister.
10. Set the drip rate per the physician order. The drip rate does not need to be exact with continuous wound irrigation.

NOTE: The irrigation rate remains constant unless the Pressure Setting is changed or if the SVED® is in Intermittent Mode.

4. Operating Instructions

Carefully read **1.3 Precautions** and **1.4 Safety Tips** before attempting to operate and adjust the SVED®.

CAUTION: The SVED® must only be used with the supplied A.C. Power Adapter. Use of any other adapter/power cord could create a shock hazard for the patient or caregiver, cause fire and/or severly damage the SVED®. If a replacement A.C. Power Adapter is needed, call Cardinal Health at 1.866.484.6798.

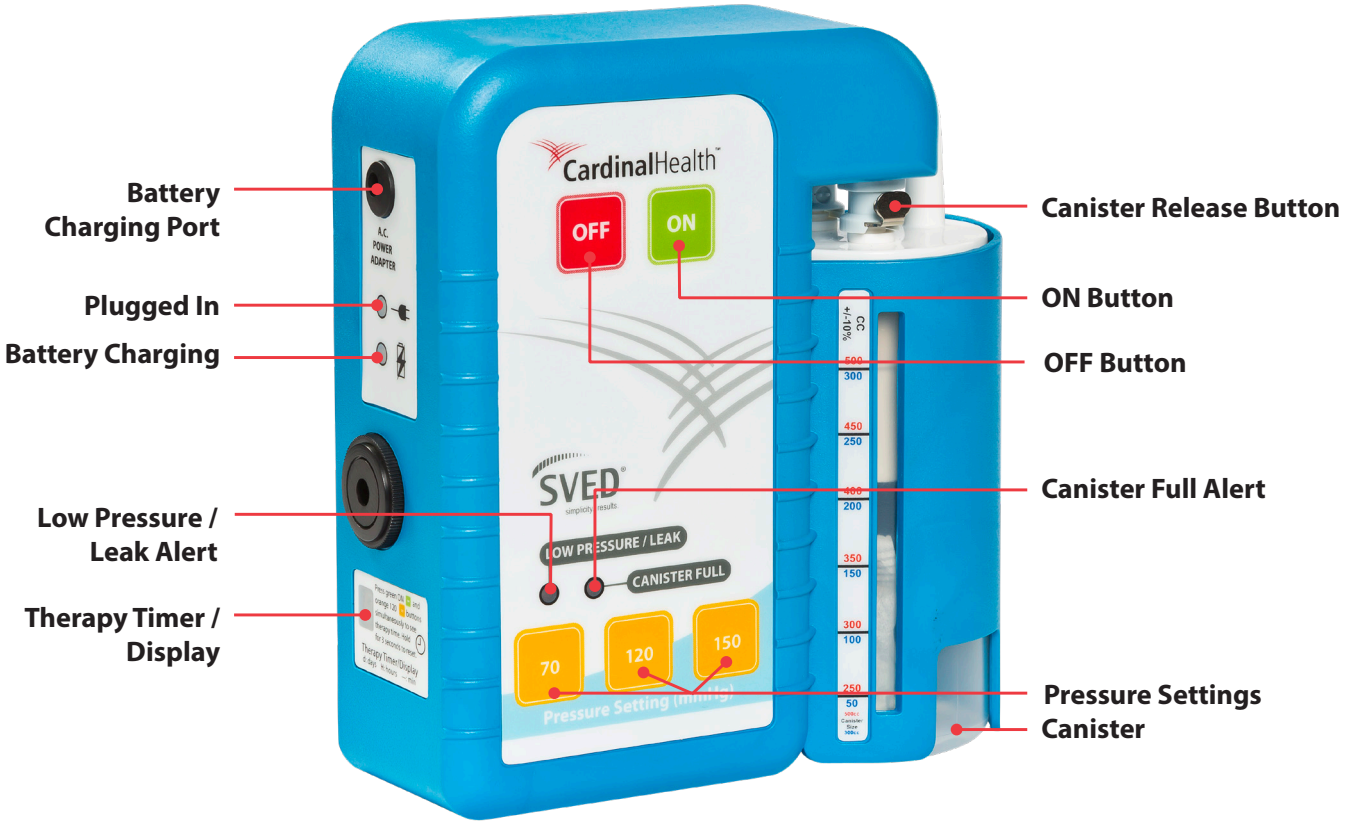

Figure 20

4.1 ON/OFF

The ON and OFF Buttons are located on the front of the SVED®.

4.2 Power-Up Procedure

1. Verify the dressing is correct, the tubing is connected and the clamp is open.
2. Keep the SVED® upright. The SVED® can be placed on a table, or attached to a pole using the pole adapter, but it is recommended to keep it level with or below the wound.

CAUTION: The clamp on the IV pole adapter should only be used on poles that are in excess of 2.2cm (0.9 in.) diameter and are securely attached to a suitable stand. To ensure stability of the SVED® on the IV pole, ensure the clamp is no higher than two times the width of the pole base. The clamp should be tightened to ensure that the SVED® cannot slide down the pole.

3. Press the ON button. All lights show for 1 second during the power-on self-test. When finished, the ON button stays green.
4. The dressing should slowly collapse, indicating the presence of negative pressure. Once dressing integrity is verified, adjust the SVED® for desired Pressure Setting.

   NOTE: It is recommended that the SVED® is connected to the A.C. Power Adapter while attempting to obtain an initial dressing seal.
5. Carefully check dressing for leaks and repair with additional drape, if necessary.
6. The SVED® should be operated at least 22 hours out of every 24-hour period. Remove the Cardinal Health™ NPWT Dressing if therapy is terminated or the SVED® is off for more than 2 hours in a 24-hour period.

4.3 Negative Pressure Wound Therapy Setting Adjustment

CAUTION: Only a physician can prescribe the proper settings and irrigation protocols for the therapy device. Failure to follow instructions or adjusting settings and performing therapy application without the express direction and/or supervision of your trained caregiver may lead to improper product performance and the potential for serious or fatal injury.

There are three Pressure Settings available: -70, -120 and -150mmHg 

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When the SVED® is turned on, the default Pressure Setting is -120mmHg, unless therapy Pressure Setting has been locked previously by the clinical caregiver, see **4.4 Negative Pressure Wound Therapy Selection Lock/Unlock**.

To change the Pressure Setting, press the desired Pressure Setting Button found on the front of the SVED®. The selected Pressure Setting button flashes, indicating the selection has been made. The Pressure Setting button continues flashing until the desired pressure has been achieved at which time the button is solid. If the Pressure Setting button begins to flash during therapy, the SVED® is unable to maintain the therapeutic setting.

4.4 Negative Pressure Wound Therapy Selection Lock/Unlock

The SVED® has a Pressure Setting lockout feature designed to prevent unauthorized individuals from changing the Pressure Setting.

Locking
To lock the SVED®, press and hold the desired Pressure Setting for three seconds until three audible beeps are heard. The SVED® is locked. Pressing any other Pressure Setting results in three beeps with no change in Pressure Setting. The Pressure Setting remains at the selected pressure even if the SVED® is powered off and on. The SVED® remains locked.

Unlocking
To unlock the SVED®, press and hold the selected Pressure Setting Button until three audible beeps are heard. The SVED® is now unlocked and Pressure Settings can be changed. When the SVED® is powered off and on, it remains unlocked and automatically reverts to the default setting of -120mmHg.

4.5 Intermittent Mode ON/OFF

The SVED® can operate in Intermittent Mode with a 5-minute "ON" and 2-minute "OFF" cycle.

To turn the Intermittent Mode on, press and hold the desired Pressure Setting Button then press the OFF Button at the same time. The SVED® beeps twice and the ON Button begins flashing, indicating the SVED® is now operating in Intermittent Mode. Release both Buttons.

To turn the Intermittent Mode off, repeat the above steps. The SVED® produces a single long beep and the ON Button is solid. The mode setting is memorized in the SVED® when the power is turned off and on. During intermittent operation, the SVED® provides desired pressure during the "ON" part of the cycle and approximately -25mmHg during the "OFF" part of the cycle. Cycling to this lower pressure while the SVED® is off helps maintain the integrity of the drape seal.

4.6 Therapy Timer/Display (s/w ver. 2.63 & higher)

The SVED® has an LED Therapy Timer/Display (**Figure 16**) for displaying two types of therapy timers: Total Time accumulated by the SVED® (non-resettable) and patient usage Therapy Time (resettable). The Therapy Timer Display uses the format: "d: days, H: hours, -: mins" and data is displayed sequentially on the display. When the SVED® is first turned ON, the total time is displayed. This timer cannot be reset and accumulates time as the SVED® is used.

After the SVED® has displayed the total time and at any time the SVED® is operating, pressing the ON button and -120mmHg buttons simultaneously starts the display of therapy time. To reset the therapy time, press and hold the ON button and -120mmHg button until the SVED® beeps three times and the Therapy Time Display indicates "d: 0, H: 00, -: 00."

4.7 Alert Volume (s/w ver. 2.63 & higher)

The volume of the alert can be adjusted. To increase the alert volume, press and hold the ON Button while simultaneously pressing the -150mmHg Button. To decrease the alert volume, press and hold the ON Button while simultaneously pressing the -70mmHg Button. The Therapy Timer Display on the side of the SVED® shows the volume level which ranges from 1 to 5. The factory set alert volume level is 2.

4.8 Battery Operation

NOTE: The SVED® continues to operate while the internal battery is charging.

Battery Life

The battery life of the SVED® with a fully-charged battery and a well-sealed dressing is up to 18 hours. The actual life is dependent on the integrity of the dressing. A leak in the dressing and using Intermittent Mode can reduce overall battery longevity.

Average Time for Recharging

After approximately 2 hours of charging, the SVED® achieves 80 percent of the total battery capacity. To ensure that the battery is fully charged, the SVED® should be connected to an outlet for approximately 3 hours.

Low Battery Alert

While running on battery, a Low Battery Alert will "chirp" every 10 seconds and the OFF button flashes when remaining capacity of the battery is less than 20 percent (see **4.9 Troubleshooting**). Typically, the SVED® continues to operate for approximately 1 hour after the Low Battery Alert sound is activated.

If the battery charge gets too low, the SVED® shuts off and negative pressure wound therapy will be discontinued. At this point, the SVED® must be plugged into an outlet using the A.C. Power Adapter for negative pressure wound therapy to resume. Once the A.C. Power Adapter is plugged in, pressing the ON button restarts the SVED®.

Recharging the Battery

Plug the A.C. Power Adapter into the Battery Charging Port on the left side of the SVED®. Plug the A.C. Power Adapter into a wall outlet.

When the SVED® is connected to an outlet, the green light next to the Plugged In symbol lights up. The yellow light next to the Battery Charging symbol lights up when the battery is charging.

NOTE: If the SVED® is plugged in and the green light does not turn on, check to make sure the outlet is working properly.

Once the battery is fully charged, the yellow light next to the Battery Charging symbol turns off, showing the battery is fully charged. When the A.C. Power Adapter is disconnected from the outlet, the SVED® automatically switches over to the internal battery and continues to operate.

4.9 Troubleshooting

Clearing an Alert Condition

To manually reset an alert, turn the SVED® off then back on. The alert clears when the power is cycled.

What you see or hear	Problem	What to do	More information
OFF Button is flashing. Single beep.	The battery is low and has approximately 30 minutes before the battery will be too low to support continued operation of the SVED®.	Plug in the SVED®. A green light shows next to the Plugged In symbol and an amber light next to the Battery Charging symbol indicates that power is going to the SVED®. The amber light turns off after the battery is fully charged.	Use only the A.C. Power Adapter that came with the SVED®. If alert continues or replacement A.C. Power Adapter is needed, call Cardinal Health at 1.866.484.6798 for more assistance.
LOW PRESSURE/LEAK indicator is lit. Single beep. Pressure Setting Button is flashing. SVED® is making more noise.	There is an air leak in either the dressing or the tubing connections. Leaks often occur over areas of moist skin, creases or folds in skin and wrinkles in the drape. They can occur if the drape snags on clothing or bed sheets.	• Clamp the tubing. • If the Low Pressure/Leak light stops, there is a leak between the clamp and the dressing — often in the dressing. Reopen the clamp before addressing the leak. • Gently press around drape to check for leaks. If leak is found, patch with extra drape material. • If Low Pressure/Leak alert continues, there is a leak between the clamp and the SVED®. Check the tubing connection at the canister. Check to ensure the canister is fully seated and locked. Check for cracks in the canister or lid separation. If found, replace the canister. • Open the clamp.	Once the leak is found and sealed, the alert resets, the Pressure Setting quits flashing and the SVED® becomes quiet.
CANISTER FULL indicator is lit. Single beep.	The canister is full.	• Visually assess the canister to see if full. If the canister is full, change the canister. • If the canister is not full, turn the SVED® off by pressing the OFF Button and then turn the SVED® back on to resume therapy.	The Canister Full alert begins when the canister is 90 percent full, but the SVED® continues to work until the canister completely fills. If the SVED® is placed on its front, fluid can cause a false Canister Full alert and the canister must be changed. If alert continues, call Cardinal Health at 1.866.484.6798 for more assistance.
Pressure will not change.	Pressure Setting has been locked.	Unlock the SVED®.	
SVED® is quiet and fluid is not moving in the tubing.	This is NOT a problem. The dressing has a good seal and the SVED® is maintaining target pressure.	No action needed.	Change the SVED® to Intermittent Mode to move fluid in the tubing to the canister.
ON Button is flashing. The SVED® is making more noise every 5 minutes.	This is NOT a problem. The SVED® is in Intermittent Mode.	No action needed.	Intermittent Mode maintains target pressure for 5 minutes and decreases to -25mmHg for 2 minutes. To change from Continuous to Intermittent Mode, press and hold the Pressure Setting Button and tap the OFF Button. Repeat to change back to Continuous Mode.

CAUTION: In the event of an emergency, please contact your treating physician, caregiver, or your local emergency responders.

NOTE: If an alert persists and cannot be resolved, please contact Cardinal Health at 1.866.484.6798 for further assistance.

5. Symbols Glossary

Symbols Recognized by Standard/Law

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 13225-1, Clause 5.1.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Manufacturer	Indicates the medical device manufacturer.
	ISO 7000-3082	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Date of Manufacture	Indicates the date when the medical device was manufactured.
	ISO 7000-2497	Graphical symbols for use on equipment		
	EN 60417-6049	Graphical symbols for use on equipment	Country of Origin	To identify the country of manufacture of products. To identify country abbreviation, see https://www.iso.org/obp/ui/#search.
	ISO 3166-1	Codes for the representation of names of countries and their subdivisions - Part 1: Country Codes		
	ISO 15223-1, Clause 5.1.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Authorized European Representative	Indicates the Authorized Representative in the European Union.
	ISO 15223-1, Clause 5.1.6	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Catalogue or Model Number	Indicates the manufacturer's catalogue number so the device can be identified.
	ISO 7000-2493	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.7	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Serial Number	Indicates the manufacturer's serial number so that a specific device can be identified.
	ISO 7000-2498	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.5	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Batch/Lot Code	Indicates the manufacturer's batch/lot code so that the batch or lot can be identified.
	ISO 7000-2492	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Use by Date	Indicates the date after which the medical device is not to be used.
	ISO 7000-2607	Graphical symbols for use on equipment		

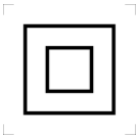
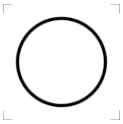
Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
IVD	ISO 15223-1, Clause 5.5.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	*In Vitro* Diagnostic Medical Device	Indicates that a medical device is intended to be used as an *in vitro* diagnostic medical device.
	IEC 60601-1, Table D.1, Symbol 10	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 7000-0434	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.7	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 7000-0632	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.8	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 7000-2620	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Keep Dry	Indicates a medical device that needs to be protected from moisture.
	ISO 7000-0626	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Fragile, Handle with Care	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 7000-0621	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.4.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Do Not Reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	ISO 7000-1051	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.6	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Do Not Resterilize	Indicates that a medical device should not be resterilized.
	ISO 7000-2608	Graphical symbols for use on equipment		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 15223-1, Clause 5.2.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterile	Indicates a medical device that has been subjected to a sterilization process.
	ISO 7000-2499	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterile Using Aseptic Techniques	Indicates medical device that has been sterilized by using accepted aseptic technique.
	ISO 7000-2500	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterilized by Ethylene Oxide	Sterilized by ethylene oxide
	ISO 7000-2501	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterilized Using Irradiation	Indicates a medical device has been sterilized using irradiation.
	ISO 7000-2502	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.5	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterilized Using Steam or Dry Heat	Indicates a medical device has been sterilized using steam or dry heat.
	ISO 7000-2503	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.9	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterile Fuid Path	To identify the presence of a sterile fluid path within the medical device when other parts of the medical device are not necessarily supplied sterile.
	ISO 7000-3084	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Keep Away From Sunlight	Indicates a medical device that needs protection from light souces.
	ISO 7000-0624	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.7	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 7000-2609	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.4.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Consult Instructions for Use	Indicates user needs to consult instructions for use.
	ISO 7000-1641	Graphical symbols for use on equipment		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	IEC 60601-1, Table D.2, Symbol 10	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Refer to Instruction Manual/Booklet	Indicates user needs to consult instructions for use.
	IEC 60601-1-2:2007, Clause 5.1.1	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Non-ionizing Electromagnetic Radiation	To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	IEC 60417-5140	Graphical symbols for use on equipment		
	IEC 60878-5140	Graphical symbols for electrical equipment in medical practice		
	ISO 15223-1, Clause 5.3.9	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Atmospheric Pressure Limits	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 7000-2621	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.6.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Non-pyrogenic	Indicates that the medical device is non-pyrogenic.
	ISO 7000-2724	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.8	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Do Not Use if Package is Damaged	Indicates that the medical device should not be used if the package holding device has been damaged or opened.
	ISO 7000-2606	Graphical symbols for use on equipment		
	ISO 7000-3079	Graphical symbols for use on equipment	Open Here	Indicates where the package can be opened and to indicate method of opening it.
	ASTM F2503	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	Magnetic Resonance (MR) Unsafe	Keep device away from magnetic resonance imaging (MRI) equipment.
	IS EN-15986:2011	Symbol for use in the labeling of medical devices. Requirements for labeling of medical devices containing phthalates.	Contains Presence of Phthalates	Indicates presence of Bis (2-ethylexyl) phthalate (DEHP).

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 15223-1, Clause 5.4.5, Annex B.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Does Not Contain Natural Rubber Latex	The medical device or the packaging of the medical device does not contain natural rubber latex.
	ISO 15223-1, Clause 5.4.5, Annex B.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Does Not Contain Natural Rubber Latex	The medical device or the packaging of the medical device does not contain natural rubber latex.
	ISO 15223-1, Clause 5.4.5	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Contains or Presence of Natural Rubber Latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	WEEE Wheeled Bin	This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose of or recycle this product in accordance with local laws or regulations that apply.
	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Type BF Applied Part	Identifies a type BF applied part complying with IEC 60601-1-11.
	ISO 7000-5333	Graphical symbols for use on equipment		
	IEC 60601-1, Table D.1, Symbol 19	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Type B Applied Part	Identifies a type B applied part complying with IEC 60601-1.
	ISO 7000-5840	Graphical symbols for use on equipment		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
IPN1N2	IEC 60601-1, Table D.3, Symbol 2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Degrees of Ingress Protection Provided by Enclosure	Manufacturer-determined degree of particle and water ingress where N1= degree of protection from particles (scale of 0-6) and N2=degree of protection from water (scale of 0-8).
	IEC 60529	Degrees of protection provided by enclosures (IP Code)		NOTE: When a characteristic numeral is not required to be specified, it is replaced by the letter ÒXÓ.
IP28	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against solid foreign objects of 12.5mm and greater, and against the effects of continuous immersion in water.
IP48	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against solid foreign objects of 1.0mm and greater, and against the effects of continuous immersion in water.
IPX8	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against the effects of continuous immersion in water.
IPX7	IEC 60529	Degrees of protection provided by nclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against the effects of temporary immersion in water.
IP22	IEC 60530	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protection against the effects of insertion of fingers and will not be damaged or become unsafe when exposed to vertically or nearly vertical dripping water.

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
℞ ONLY	21 CFR Part 801.1(c)(1)(i)F	Labeling - Medical devices; prominence of required label statements	Prescription Use Only	Requires prescription for sale in the United States and is used in place of the statement below: **CAUTION**: Federal law restricts this device to sale by or on the order of a physician, dentist or licensed practitioner.
	21 CFR Part 801.109	Labeling - Prescription devices		
CE	Directive 93/42/ EEC Articles 4, 11, 12, 17 Annex 12	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive.	Signifies European technical conformity.
	Directive 93/68/ EEC	CE Marking		
	IEC 60417-5172 Section 7.2.6	Class II equipment	Marking requirements for Class II Equipment	Power adapter meets the safety requirements specified for Class II equipment according to IEC 61140.
	ISO 7000-2616	External cord connected	External Cord Connected	Indicates that device is connected to an external power source.
	ISO 7000-5008	OFF (power)	OFF (Power)	To indicate disconnection from power.
	ISO 7000-5007	ON (power)	ON (Power)	To indicate connection to power.
	ISO 7000-5417	Programmable duration	Programmable Duration	To identify the control of a programmable timer to start an operation at a specific point in time and to stop the operation at a specific point in time or after a specific duration; or to identify a display of the programmed or to-be-programmed duration.

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 7000-5546	Battery check	Battery Check	To identify the battery condition indicator.
	ISO 7000-0623	This way up	This Way Up	To indicate correct upright position of the transport package.

Symbols Not Recognized by Standard or Law

Symbol	Guidance	Guidance	Symbol Title	Explanatory Text
	INDA and EDANA Flushability Guidelines	INDA and EDANA Flushability Guidelines	Do Not Flush	Do not flush in toilet.
				This container can and should be recycled.
			Powder Free	Gloves are powder free.
			Synthetic	Indicates medical device contains synthetic latex.
				This glove has been tested for resistance to permeation of various chemotherapy drugs per ASTM D6978, "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs."

Symbol	Guidance	Guidance	Symbol Title	Explanatory Text
LAB CHEMICAL TESTED				This glove has been tested for permeation of various chemicals per ASTM F739, "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact."
 1 Pair of Gloves			1 Pair of Gloves	Contains a pair of gloves.
			Russian Registration Mark	Signifies technical conformity in Russia.
			Open Arrow	Open at arrow.
			Peel Here	Peel here to open package.
 Pouch Opening			Pouch Opening	Directions on how to open pouch.
 1 Single Glove			1 Single Glove	Contains a single glove.
			UL Listed	UL has tested representative samples of a product and determined that it meets UL's requirements. These requirements are based on UL's published and nationally recognized Standards for Safety.
			UL Listed	Product is certified under UL's Listing and Classification services and for UL certifications for Canada and the USA.

Symbol	Guidance	Guidance	Symbol Title	Explanatory Text
			Device Plugged into an Outlet	Indicates that device is connected to an external power source.
			Battery Charging	Device is plugged into an outlet and the internal battery is charging.

6. Specifications

SVED®

Dimensions ..... 19.4 x 7.2 x 18cm (7.6 x 2.8 x 7.1 in.)
Weight ..... 0.9kg (2.0 lb.)
Therapy Settings ..... -70, -120, -150mmHg

Medical Equipment with respect to electric shock, fire, and mechanical hazards only in accordance with IEC60601-1.

IEC Classification

- Medical Equipment
- Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Continuous Operation
- Type B Applied Part
- Class II Internally Powered Equipment
- IP22 - *Drip proof from rain falling at 15-degree angle*

Battery

Duration (Fully Charged) ..... up to 18 hours

Electrical

External Power Supply Input 100-240VAC, 50-60Hz, 700mA
External Power Supply Output 15VDC, 2Amp

SVED® Storage Conditions

Temperature Range ..... -12°C (10°F) to 43°C (110°F)
Relative Humidity Range ..... 65 +/-20% (45% to 85%)
Atmospheric Pressure Range ..... 50kPa to 110kPa
Time to Warm from -12°C to 20°C Before Use ..... 120 minutes
Time to Cool from 43°C to 20°C Before Use ..... 120 minutes

SVED® Operating Conditions

Temperature Range ..... 4°C (40°F) to 32°C (90°F)
Relative Humidity Range ..... 65 +/-20% (45% to 85%)
Atmospheric Pressure Range ..... 50kPa to 110kPa
Service Life ..... 3 years

Dressing Sets and Accessories

Expiration Date ..... 3 years from date of manufacture

CAUTION: Federal law restricts this device to sale by, or on the order of, a physician.

6.1 Electromagnetic Compatibility

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic Environment**
Harmonic emissions IEC 6100-3-2	Class A	The SVED® is suitable for use in all establishments, including medical facilities, domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
RF emissions CISPR 14-1	Complies	The SVED® is not suitable for interconnection with other equipment.

Recommended separation distance between portable and mobile RF communications equipment and the SVED®

The SVED® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SVED® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SVED® as recommended below, according to the maximum output power of the communications equipment.

Output Power of Transmitter in watt(s)	**Separation distance according to frequency of transmitter in meter(s)**		
	150kHz to 80MHz	**80MHz to 800MHz**	**800MHz to 2.5GHz**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 percent.
Electrical fast transient/burst	±2kV for power supply lines ±1kV for input/output	±2kV for power supply lines ±1kV for input/output	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1kV line to line ±2kV line to earth	±1kV line to line ±2kV line to earth	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	<5% U_T (95% dip in U_T) for 5 sec.	<5% U_T (95% dip in U_T) for 5 sec.	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3V rms 150kHz ~ 80MHz 3V/m 800MHz ~ 2.5GHz	3V rms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the SVED® including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80MHz and 800MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SVED® is used exceeds the applicable RF compliance level above, the SVED® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SVED®. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

7. Additional Parts

7.1 Replacement Product

Power Supply

A.C. Power Adapter 47-9000

7.2 Disposables and Accessories

Dressings

Cardinal Health™ NPWT Small Foam Dressing Kit 10 x 8 x 3cm (10 per case) 47-1702
Cardinal Health™ NPWT Medium Foam Dressing Kit 20 x 12.5 x 3cm (10 per case) 47-1701
Cardinal Health™ NPWT Large Foam Dressing Kit 25 x 15 x 3cm (10 per case) 47-1700
Cardinal Health™ NPWT X-Large Foam Dressing Kit 58.5 x 33 x 3cm (10 per case) 47-1703
Cardinal Health™ NPWT Small White Foam Dressing 9.5 x 9.5 x 0.5cm (10 per case) 47-1751
Cardinal Health™ NPWT Large White Foam Dressing 35 x 25 x 0.635cm (5 per case) 47-1755

Canisters

Canister with Gel, 300cc (10 per case) 47-4000
Canister with Gel, 500cc (10 per case) 47-4500
Canister without Gel, 300cc (10 per case) 47-4100

Accessories

NPWT Irrigation Delivery Kit (5 per case) 47-6500
NPWT Irrigation Tubing with SpeedConnect™ (5 per case) 47-6000
NPWT Bridging Kit (5 per case) 47-1704
SVED® IV Pole Holder (1 per case) 47-5500
SVED® Carrying Case (1 per case) 47-9500
NPWT Tubing with SpeedConnect™ (10 per case) 47-2000
NPWT Polyurethane Drape (10 per case) 47-7000
NPWT SensiSkin™ Drape (10 per case) 47-7100

NOTE: Part numbers for Canisters, Dressings and Disposable Accessories may be obtained by visiting the Cardinal Health website (www.cardinalhealth.com).

NOTE: In order to assure the highest safety, quality and efficacy of the products, the SVED® should only be used with Cardinal Health NPWT products listed above.

8. Questions & Information

For questions or additional information on the SVED®, please contact your local Cardinal Health representative, or:

Call our customer service at 1.866.484.6798

Cardinal Health
Waukegan, IL 60085
www.cardinalhealth.com

Always consult a physician and product instructions for use prior to application.

CAUTION: Federal law restricts these devices to sale by, or on the order of, a physician.

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