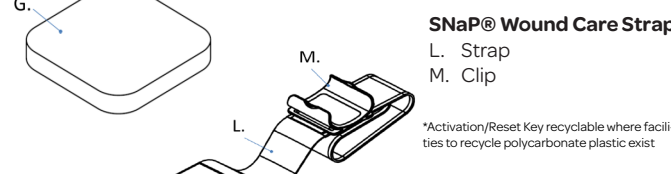
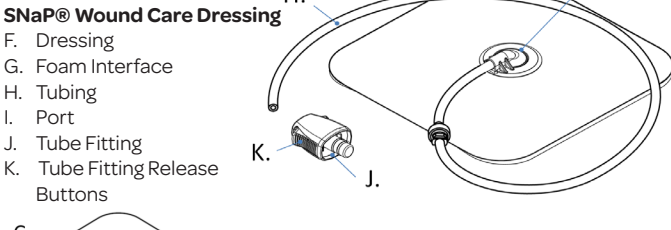
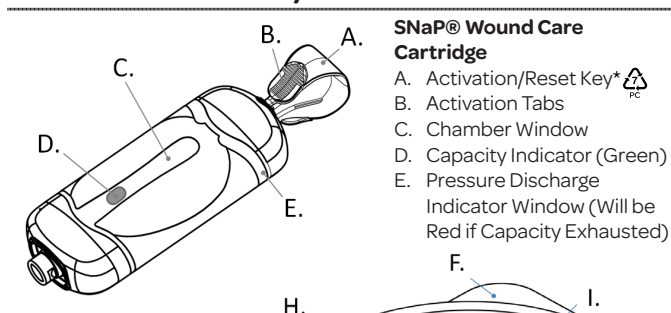


SNaP® Wound Care System Features



System Description

The SNaP® Wound Care System includes a non-powered, disposable suction device and a dressing kit for medical applications.

Step A1 Prepare the wound bed and periwound skin per institutional protocol and irrigate wound bed thoroughly with normal saline.

Step A2 If necessary for the particular wound, apply a skin protectant to the surrounding skin.

Step A3 If necessary for the particular wound, cut a single layer of wide mesh, non-adherent to the size of wound and place on wound bed.

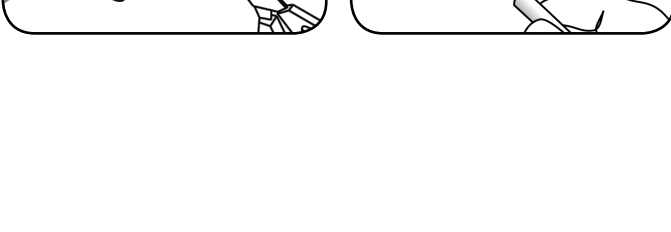
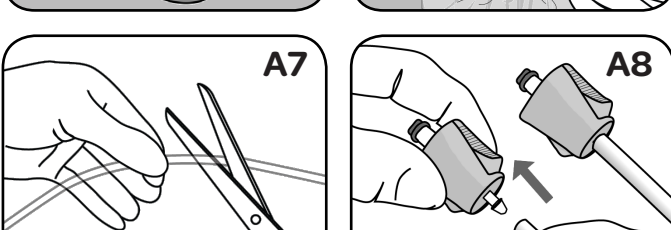
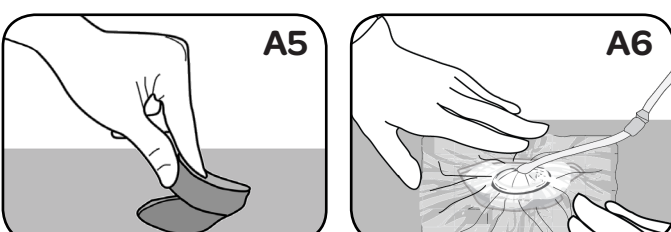
Step A4 Cut the Foam Interface to fit the size and shape of the wound

! Do not cut foam directly over wound bed to avoid loose fragments from falling into wound. Brush off foam edges after cutting to remove any loose fragments

Step A5 Place Foam Interface into wound cavity. Foam Interface should fill the wound cavity and extend above the wound margins.

! Count and record the number of pieces used to ensure the same number of pieces are removed during dressing removal. If a piece of foam is used in a tunnel, ensure the foam is in contact with foam in the primary wound bed. Do not place foam into blind or unexplored tunnels.

Step A6 Place the SNaP® Wound Care Dressing over the wound and seal. Ensure that the center opening of the Port on the Dressing is placed over the foam interface. Ensure that a minimum of 1 cm of intact skin around the wound is adhered to the Dressing to maintain a proper seal.



Indications for Use

The SNaP® Wound Care System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of excess exudates, infectious material and tissue debris. The SNaP® Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), surgically closed incisions, flaps and grafts.

Contraindications

- Do not place the SNaP® Wound Care System over:
- Actively infected wounds
 - Inadequately drained wounds
 - Inadequately debrided wounds
 - Exposed blood vessels, anastomotic sites, organs, tendons or nerves
 - Wounds containing malignancy
 - Fistulas
 - Osteomyelitis
 - Actively bleeding wounds

Warnings

- It is a condition of use that the device will be operated under the supervision of a qualified and authorized clinical caregiver and that the user has the necessary training and knowledge of the specific medical application for which the SNaP® Wound Care System is being used. Failure to follow these conditions and/or to carefully read and follow all of the therapy unit usage and dressing application instructions and the safety information prior to each use may lead to improper device performance and the potential for serious or fatal injury.
- The SNaP® Wound Care System has not been studied on pediatric patients.
 - For single patient use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or re-sterilization will compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury or illness.
 - Do not use the SNaP® Wound Care Dressing on patients who are allergic to adhesives.
 - Do not reset the SNaP® Wound Care Cartridge if the Cartridge contains wound exudate. Instead, replace the Cartridge with a new one.
 - Never leave the SNaP® Wound Care Dressing in place without active negative pressure therapy.

Step A7 Cut the Dressing Tubing to the desired length.

Step A8 Fully insert the Tube Fitting into the Tubing. Do NOT remove the cap at the end of the Tube Fitting.

Step A9 Connect the SNaP® Wound Care Cartridge to the Tube Fitting using both hands.

Step A10 To activate the Cartridge, remove the Activation/Reset Key from the Cartridge by pressing the Activation Tabs on its side and pulling it out.

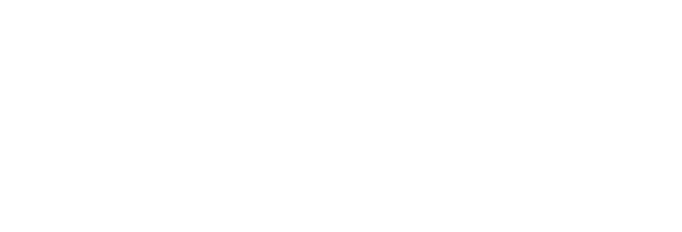
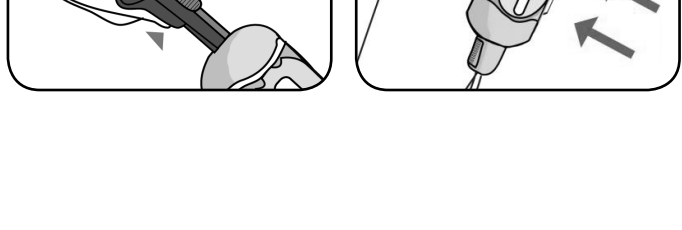
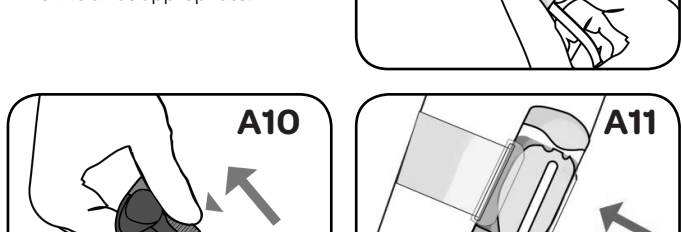
Step A11 Secure the SNaP® Wound Care Cartridge to the patient's extremity or belt using the SNaP® Wound Care Strap.

! When the Strap is placed around an extremity, take care to ensure that the Strap is not placed too tightly as this may cause discomfort or potentially decrease blood flow to the extremity.

Step A12 Check Negative Pressure Operation. The SNaP® Wound Care System is working properly if:

- Green Capacity Indicator is both visible and stationary in the Chamber Window
- Dressing has a 'sucked down' appearance
- The Dressing feels hard to the touch

It is recommended that the Dressing be changed at a minimum of two times per week, with frequency adjusted by the clinician as appropriate.



- If the RED indicator becomes visible, negative pressure is no longer active.
- Complete hemostasis should be achieved prior to placement of the Dressing on wound as bleeding may interfere with the normal function of the SNaP® Wound Care System.
- Extra care and monitoring is required for patients who are on blood thinners such as Heparin, Coumadin, or platelet-aggregation inhibitors because bleeding may interfere with the normal function of the SNaP® Wound Care System.
- The Dressing should not be placed on actively infected wounds or bone as this may worsen infections.
- Care should be exercised if using the SNaP® Wound Care System on spinal cord injury patients; stimulus from placement, initiation or cessation of negative pressure may cause autonomic hyperreflexia.
- The Dressing should be removed prior to defibrillation if near the area of pad/paddle placement. Fluid and electrolyte loss may result from highly exudative wounds. Close monitoring of electrolytes may be indicated in such cases.
- Patients with severe malnutrition may be at higher risk for fluid loss from their wounds and may require more frequent monitoring.
- To prevent ischemia, the Dressing should not be circumferentially placed around appendages, and the SNaP® Wound Care Strap should be worn as loosely as possible.
- Discard Cartridge, Dressing or other dressing materials if packaging is open or damaged.
- Do not place the dressing materials into hidden or undetected tracts.
- The primary foam interface should not be in direct contact with delicate structures such as tendons, ligaments and nerves. Use of a wide meshed non-adherent, bio-engineered tissues or natural tissue structures should be utilized to cover and protect delicate structures.
- During initial placement of the foam interface, count the total number of pieces placed in the wound and document this number per facility protocol.
- During removal, remove all pieces, as documented during initial placement, and any fragments are removed from the wound. Unintentional dressing material retention, for periods longer than recommended, may result in infection or other adverse events.
- It is recommended that the Dressing be changed at a minimum of two times per week, with frequency adjusted by the clinician as clinically indicated.
- Clinicians, caregivers and patients should frequently monitor the patient's wound, surrounding tissue and secretions to ensure that the Dressing is not causing maceration or tissue necrosis. Infection can be severe and result in septic or toxic shock and/or fatal injury.
- The SNaP® Wound Care Cartridge is not safe for use with magnetic resonance imaging (MRI) equipment. Do not use inside an MRI suite.

! Precautions

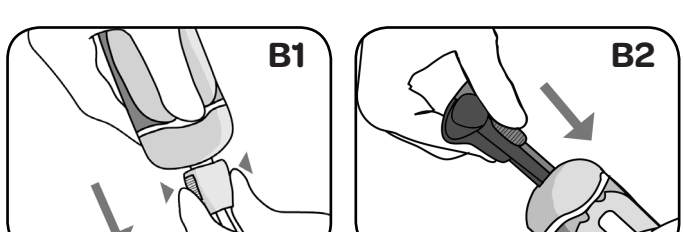
- Patient size and weight should be carefully considered when prescribing the SNaP® Wound Care System.
- Care must be taken to position the Cartridge and Dressing tubing appropriately to prevent the risk of tubing and/or falling.
- To reduce the risk of transmission of blood-borne pathogens, apply standard precautions for infection control with all patients, per institutional protocol. In addition to gloves, use gown and goggles if exposure to body fluids is likely.
- The SNaP® Wound Care System may not be appropriate for treatment of noncompliant or combative patients.
- Patients may bathe while using the SNaP® Wound Care System. However, patients should avoid getting the SNaP® Wound Care System wet.
- The SNaP® Wound Care Cartridge and Strap are provided non-sterile and should not be sterilized.
- The SNaP® Wound Care Cartridge and Dressing should be stored at room temperature only and should not be exposed to excessive cold or heat.

! Regular visual inspection of the SNaP® Wound Care System is recommended so that any loss in negative pressure delivery can be recognized in a timely manner. **At a minimum the SNaP® Wound Care Cartridge should be inspected once every 8 hours.**

Resetting the SNaP® Wound Care Cartridge (B)

If the SNaP® Wound Care Cartridge becomes retracted and the Red Pressure Discharge Indicator becomes visible before an airtight seal is established, reset the SNaP® Wound Care Cartridge using the following steps:

Step B1 Remove the Tube Fitting from the Cartridge by pressing the Release Buttons and pulling the Tube Fitting out of the Cartridge. Do not remove the Tubing from the Tube Fitting.



Step B2 Connect a new Cartridge to the Tube Fitting using both hands.

Troubleshooting

Problem	Possible solutions
Airtight seal is not present at wound Dressing, and Red Pressure Discharge Indicator IS visible. OR Green Capacity Indicator does not remain stationary in Chamber Window.	<ul style="list-style-type: none"> Check that tubing connections are secure. Smooth Dressing with fingers to flatten wrinkles. Seal Dressing edges with additional adhesive drapes such as 3M™ Tegaderm™. Apply ostomy paste to Dressing edge to seal difficult anatomical locations.
Airtight seal is not present at wound and Green Capacity Indicator is stationary.	<ul style="list-style-type: none"> Examine tubing for possible occlusion or kinks. If found, straighten tubing or replace SNaP® Wound Care Dressing. Occlusion may reside in wound dressing. Replace wound dressing.

Warranty and Limitation of Liability

Spiracur Inc. warrants that the product when delivered is free from defect in materials and workmanship and conforms to the manufacturer's then-current version of its published specifications. This warranty applies for the period of time up to and including the expiration date for the product. At its option, Spiracur Inc. will replace or provide a refund for any product manufactured by it and found to be defective, so long as the product is returned to Spiracur Inc. according to the return goods policy. Spiracur Inc. shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of, or inability to use, its product.

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Physician Instructions

The SNaP® Wound Care Cartridge is available in three models each capable of creating a preset negative pressure level (-75, -100, and -125 mmHg) that cannot be changed. Prior to placement of the SNaP® Wound Care System, the clinician must assess how to optimally use the System for an individual wound.

It is important to carefully evaluate the wound and patient, to ensure that the Indications For Use are met.

These general guidelines should be adhered to:

- The negative pressure level should never be painful to the patient. If a patient reports discomfort with a certain pressure level, then a lower negative pressure Cartridge should be used until the patient reports comfort with the device.
- If the patient reports discomfort with the -75 mmHg model then therapy with the SNaP® Wound Care System should be discontinued.

The physician instructions to the clinician/caregiver should contain:

- Negative pressure level to be used
- Dressing change frequency
- Adjunctive dressings to be used
- Patient training and guidance
- Desired treatment duration and/or end-point, if any

Review the label instructions with the patient and ensure that the patient understands them adequately.

Ensure that the patient can adequately answer the following questions before release from the clinic:

Step B2 Insert the Activation/Reset Key into the slot on the end of the Cartridge and push the Activation/Reset Key forward into the Cartridge until it locks into place.

Step B3 Follow instructions from Step A9 above.

If problem still exists after all solutions have been attempted, remove Dressing and Foam Interface. Apply a moist gauze bandage or similar over the wound and notify your physician.

Airtight Seal is Present at wound if:

- Green Capacity Indicator is both visible and stationary in the Chamber Window
- Dressing has a sucked down appearance
- The Dressing feels hard to the touch

Replacing the SNaP® Wound Care Cartridge (C)

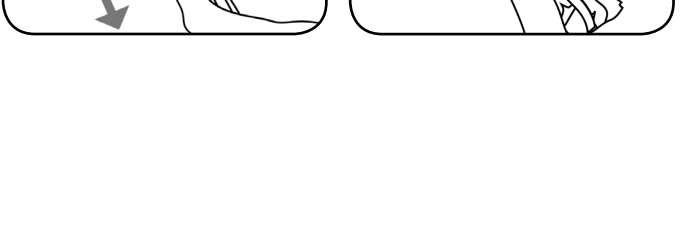
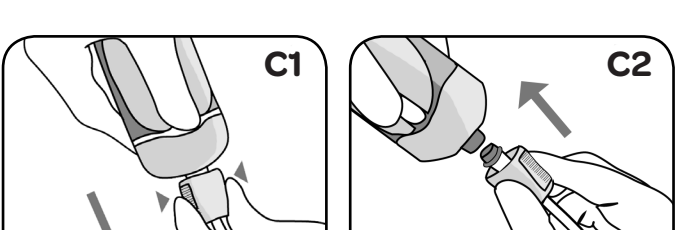
If the Red Pressure Discharge Indicator is visible, the SNaP® Wound Care Cartridge no longer has Negative Pressure Delivery Capacity and must be replaced with a new Cartridge following the steps below if further or continued treatment with the SNaP® Wound Care System is desired or indicated by a physician.

Step C1 Remove the Tube Fitting from the Cartridge by pressing the Release Buttons and pulling the Tube Fitting out of the Cartridge. Do not remove the Tubing from the Tube Fitting.

! Do NOT remove the cap at the end of the Tube Fitting.

Step C2 Connect a new Cartridge to the Tube Fitting using both hands.

Step C3 Follow instructions from Step A10 Above. Discard the used Cartridge according to institutional protocol.



- How frequently to visually inspect the Cartridge (at a minimum every 8 hours).
- When to replace the Cartridge.
- How to replace the Cartridge. Refer to section: 'Replacing the SNaP® Wound Care Cartridge (C)'.
- How to identify a leak in the Dressing and what actions to take to address it.

Dressing Application and Cartridge Activation

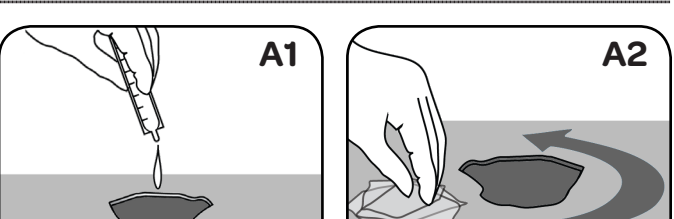
All wounds are unique. The clinician treating the wound needs to make an individual assessment of the optimal dressing and application method.

! Inspect all packaging before use and do not use products from packages that are open or damaged.

Ensure you have the following dressing items:

- SNaP® Foam Interface
- SNaP® Wound Care Dressing
- Wide mesh, non-adherent (if required)

System Application Instructions (A)



Cleaning

If the SNaP® Wound Care System becomes soiled, follow the general guidelines below:

- Clean with a damp soft cloth.
- Dry using a dry cloth.
- Avoid using corrosive or abrasive chemicals.

! Do not immerse the SNaP® Wound Care System in fluid.

Explanation of Symbols Used

STERILE R	Sterilized Using Irradiation	NON-STERILE	Non-sterile	!	See Instructions for Use
	Date of manufacture		Expiration Date	LOT	Lot Number
	Legal Manufacturer	LATEX	Latex Free	REF	Catalog Number
Rx Only	CAUTION: Federal law (USA) restricts this device to sale by or on order of a physician		For Single use only. Do not reuse		
PHT DEHP	Contains or Presence of Phthalates: Bis (2-ethylhexyl) phthalate (DEHP). The potential effects of phthalates on pregnant/nursing women or children have not been fully characterized and there may be concern for reproductive and developmental effects.				

