Smith+Nephew

RENASYS◊ TOUCH
Negative Pressure Wound Therapy System

RENASYS◊ EDGE
Negative Pressure Wound Therapy System

PICO◊
Single Use Negative Pressure Wound Therapy System

RENASYS and PICO
Negative Pressure Wound Therapy Systems

# Clinical guidelines

## Life unlimited

At Smith+Nephew, we believe our bodies shouldn't hold us back from who we are and what we can do.

We are passionate about pioneering innovative technology to support healthcare professionals to redefine recovery for their patients.

Our wound care portfolio aims to help healthcare professionals through innovative products and services, to deliver accelerated healing or preventing wounds, and to do more with less, such as enabling patients to be treated faster requiring fewer resources, or moved from acute to homecare settings.

**19,000**

Employees supporting healthcare professionals worldwide

**121,963**

Medical training sessions provided by Smith+Nephew in 2022

Our technology takes the limits off living, helping a patient back to a normal life

# Contents

# Guideline overview and application

The Smith+Nephew Negative Pressure Wound Therapy (NPWT) clinical guidelines are designed to provide healthcare professionals with comprehensive information on the clinical use, application, and management of traditional and single-use negative pressure wound therapy systems.

These guidelines serve as a resource for clinical decision-making, ensuring safe and effective treatment outcomes for patients requiring NPWT.

These guidelines are intended for a wide range of healthcare providers involved in wound or incision care management, including surgeons, physicians, physician assistants, nurses, wound care specialists, and technicians.

They are also a valuable tool for training healthcare staff in the use of the Smith+Nephew NPWT portfolio.

The guidelines outlined in this document do not override clinical judgment for patient care.

## Purpose

Support effective use of NPWT for optimal patient outcomes

## Target audience

- Surgeons
- Mid-level providers

# Introduction to wound management

## Clinical landscape of wound care

In the US over 8.2 million people annually are affected by chronic wounds, costing the healthcare system between 28.1 and 96.8 billion. (based on Medicare beneficiaries).[1]

This rate is expected to rise owing to an aging demographic that will likely require more joint replacements and a growth in obesity, diabetes, and vascular disease, which may result in a higher incidence of wound complications.[2]

Effective wound management requires thorough evaluation of both patient and wound to tailor the best treatment plan, addressing any barriers to healing before choosing a suitable therapy.[3,4]

Advanced therapies like NPWT can help to achieve good clinical and patient outcomes while being cost-effective.[5] NPWT has been shown to:

- Promote granulation tissue formation[5]
- Protect the wound from the outside environment[5]
- Promote moisture balance within the wound bed[5]

At-risk orthopedic patients experience surgical incision complications at rates

**3 – 10x higher**

than the general population[8,9]

**68% of individuals**

with chronic leg ulcers experience negative effects on their lives, such as feelings of loneliness and isolation[6]

**$25+ billion**

Annual cost to the healthcare system on wound-related complications[7]

**NPWT Portal**

**Smith+Nephew Academy Online**

## Principles of wound bed preparation

Incorporating the TIME principles of wound bed preparation may contribute to achieving desired outcomes.

## TIME Clinical Decision Support Tool (CDST)

The TIME CDST tool is an updated framework for wound care management, emphasizing a comprehensive approach to address the current challenges in wound care.[4]

It provides a systematic assessment to enhance patients healing outcomes by assisting clinicians with:[3]

1. Initial wound assessment
2. Diagnosis
3. Determine appropriate interventions
4. Continuous wound monitoring

The TIME CDST integrates the well-established TIME principles and follows a simple A, B, C, D and E approach.[3] A copy of the tool is available on page 7.

### TIME principles:[3]

| T | I | M | E |
|---|---|---|---|
| Tissue management: non-viable or deficient | Infection/ inflammation | Moisture imbalance | Edge, which is not advancing or undermining |

### ABCD approach:[10]

| A | B | C | D | E |
|---|---|---|---|---|
| Assess patient, wellbeing and wound | Bring in the multidisciplinary team and informal carers to promote holistic patient care | Control or treat underlying causes and barriers to wound healing | Decide appropriate treatment and determine short-term goals | Evaluate and reassess the treatment and wound management outcomes |

Adapted from Dowsett and Ayello, 2004

### Evidence based

The TIME CDST tool's development involved expert consensus and was informed by a survey conducted at the European Wound Management Association conference, which highlighted the need for a standardized, easy-to-use framework for wound assessment and management. This approach is supported by a growing body of research and clinical practice guidelines that advocate for a multifaceted and patient-centered approach to wound care, aiming to improve outcomes and reduce healthcare costs.[3]

# TIME wound management pathway

## Assess patient, wellbeing and wound

Establish diagnosis and baseline characteristics for appropriate support and comorbidities that may impact healing. Record wound type, location, size, wound bed condition, signs of infection / inflammation, pain location and intensity, comorbidities, adherence to treatment

## Bring in multi-disciplinary team and informal carergivers to promote holistic patient care

Record referral to others such as surgical team, wound specialist, dietician, pain team, vascular and/or diabetes specialists, podiatrist, physical therapist, family caregivers and counselor

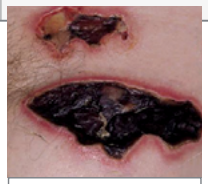
## Control or treat underlying causes and barriers to wound healing

Record management plan for: systemic infection, diabetes, nutritional problems, edema, incontinence, mobility, vascular issues, pain, stress, anxiety, non-adherence / adherence with offloading and compression, lifestyle choices

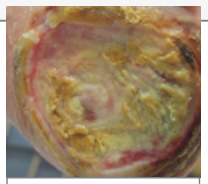
## Decide appropriate treatment and determine short-term goals

### T – Tissue non-viable[3-4]

1. ARE THERE BARRIERS TO WOUND HEALING?



Necrotic/Eschar



Slough

2. SELECT PRIMARY & SECONDARY INTERVENTIONS

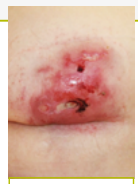
- Cleansing and debridement
- Surfactant, sharp / surgical or mechanical, autolytic or enzymatic, biological / larval

3. WOUND MANAGEMENT OUTCOME

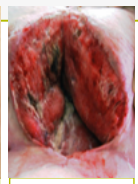
- Viable healthy wound bed

### I – Infection and/or Inflammation[3-4]

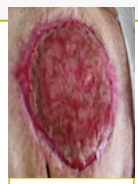
1. ARE THERE BARRIERS TO WOUND HEALING?



Local infection



Local infection



Local infection

2. SELECT PRIMARY & SECONDARY INTERVENTIONS

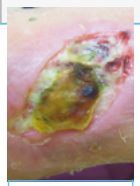
- Manage bioburden
- Antimicrobial* (topical antiseptic, and / or antibiotic therapy†)

3. WOUND MANAGEMENT OUTCOME

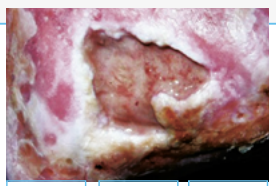
- Non-inflamed, non-infected wound

### M – Moisture imbalance[3-4]

1. ARE THERE BARRIERS TO WOUND HEALING?



Dry wound



Low | Moderate | High

2. SELECT PRIMARY & SECONDARY INTERVENTIONS

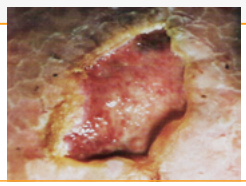
- Restore moisture balance
- Hydrogel*, hydrocolloid
- Foam, super absorbent, gelling fibre, NPWT‡
  - Hydrocolloid, alginate
  - Alginate

3. WOUND MANAGEMENT OUTCOME

- Optimal moisture balance

### E – Edge of wound non-advancing[3-4]

1. ARE THERE BARRIERS TO WOUND HEALING?



Non-advancing or abnormal wound edge

2. SELECT PRIMARY & SECONDARY INTERVENTIONS

- Promote epithelialization and healthy periwound skin
- NPWT‡ – Atraumatic wound contact layer, cellular or tissue-based products, skin care and adjunct treatment according to wound type

3. WOUND MANAGEMENT OUTCOME

- Advancing edge of wound

*Use appropriate secondary dressing as per your local protocol; †Where systemic infection is present, then it must be treated systemically and not just topically; ‡Negative Pressure Wound Therapy.

## Evaluate and reassess the treatment and wound management outcomes

Evaluate: Record wound progression within given timelines. **Flag** if no change, go back to A, B, C and change treatment where indicated

Developed with the support of Glenn Smith[3] and Moore et al. 2019[4]

# Fundamentals of Negative Pressure Wound Therapy

## Overview

NPWT can support wound bed preparation by promoting optimal wound moisture and advancing edges of the wound.[5,21]

NPWT is considered a gold standard for the treatment of acute and chronic open wounds and is well-established in the treatment of surgical incisions. Emerging evidence suggests NPWT enhances patient outcomes through improvement in wound healing rate, reduces clinical time and prevents hospital admission/readmission.[5]

It helps to reduce healing time for wounds and surgical site complications such as:

- Seroma[11,12]
- Surgical site infection[13]
- Dehiscence[13]
- Prolonged drainage[13]

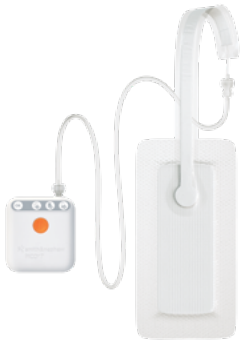
**The two main types of NPWT are traditional NPWT (tNPWT) and single-use NPWT (sNPWT).**

**These modalities are complementary, allowing for transitions between devices as the patient's wound heals and the amount of wound exudate decreases. The decision to switch is often caused by a reduction in wound size or exudation.[5]**

## Smith+Nephew NPWT devices

### Traditional: RENASYS◊ NPWT Systems

### Single-use: PICO◊ NPWT System



## Differences between traditional and single-use NPWT[14]

### Traditional NPWT (tNPWT)

- Multi-patient use
- Fluid is drawn into a canister via tubing
- Uses wound filler to distribute negative pressure (commonly gauze or foam, but others are available)
- Adjustable pressure with continuous and intermittent modes of operation
- Rechargeable lithium ion battery powered
- For use in acute and post-acute settings

### Single-use NPWT (sNPWT)

- Single-patient use and disposed of following treatment
- Fluid is handled through evaporation from the outer layer of the dressing
- Wound filler is optional to distribute negative pressure*
- Some devices use a small canister and some use a dressing to manage fluid and exudate
- Pressure is applied continuously and is not usually adjustable
- Often battery powered
- Suitable for use in the hospital or homecare setting

*Recommended for treating open wounds that are 0.5cm to 4.5cm in depth. Wounds greater than 0.5cm (1/4in) in depth are likely to require a foam or gauze NPWT filler to ensure adequate treatment of all the wounds surfaces. Wounds greater than 2cm (3/4in) in depth must be treated with the use of a filler along with a single-use negative pressure wound therapy (sNPWT) to ensure adequate contact with the wound.

## Mechanism of action

NPWT uses sub-atmospheric pressure to promote a wound healing environment which may lead to a faster and more effective recovery.[5]

**1. Wound healing promotion[5]**
- Encourages wound closure
- Improves granulation tissue formation
- May decrease bacterial burden

**2. Fluid management[5]**
- Exudate removal
- Promotes moisture balance

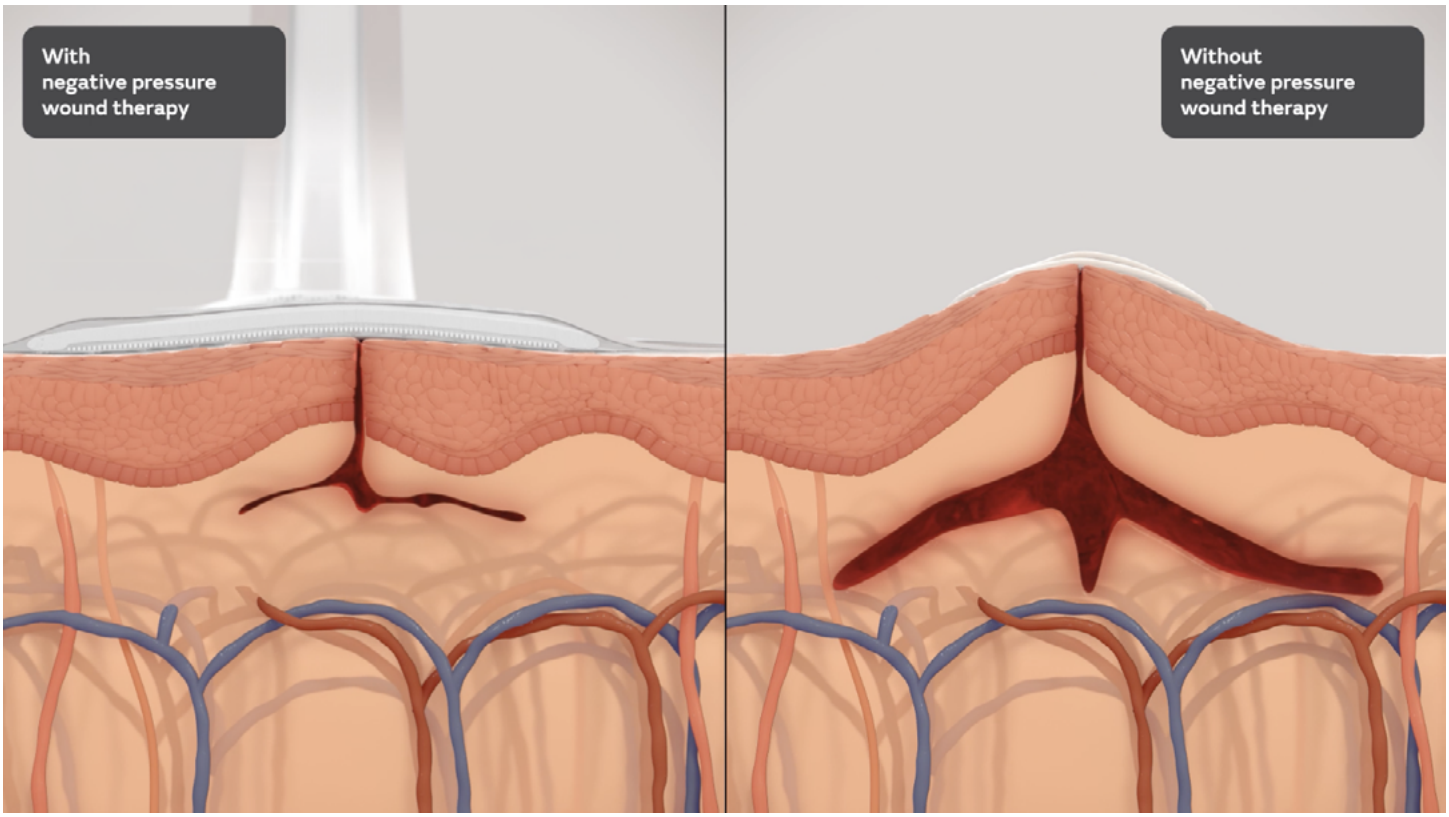
**3. Edema and infection control[5,11,12,15–17]**
- Reduced edema
- May decrease bacterial burden (also contributes to wound healing promotion)

**4. Physical protection and patient comfort[5,11,12,15–17]**
- Reduces lateral tension*
- Protection from outside environment
- May decrease frequency of dressing changes

Adapted from Wounds International, 2023.

*MOA is specific to closed surgical incisions

## Difference in surgical site healing with NPWT and without



## Optimization of NPWT

Using NPWT promptly can lead to earlier patient discharge, higher satisfaction, reduced workload for caregivers, and lower healthcare costs.[5]

### The effective use of NPWT replies on two key factors:

1. Good clinical assessment of the patient and their wound
2. Development of a plan for wound closure which includes:
   – Debridement
   – When to start/stop NPWT

## Three steps to optimize NPWT in open wounds and closed surgical incisions

1. **Debride wound**[57]

   **Caution:** If necrotic tissue with eschar is present post debriding the wound, NPWT is contraindicated.

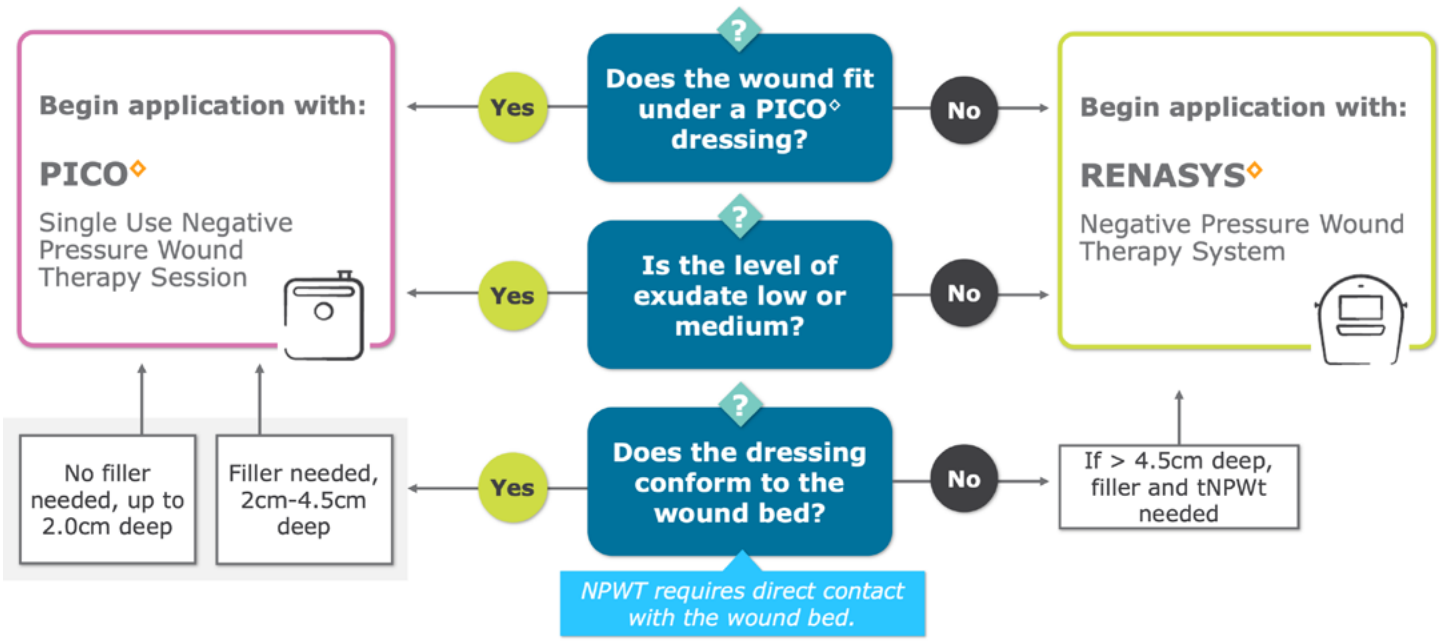
2. **Use NPWT**[5,58]

   Assess wound with every dressing change using TIME (CDST) tool

3. **Know when to stop/change treatment**[5,19]

   When established goal of therapy has been met or if no improvements has been documented for two weeks (open wounds)

## Clinical decision tree for open wounds




* Wounds must not contain exposed arteries, veins, nerves or organs † Wounds should generally be no more than 4.5cm in depth and must not contain exposed arteries, veins, nerves or organs ‡ p=0.046; n=31; Compared to black foam in acute post traumatic wounds.

# RENASYS◊ Negative Pressure Wound Therapy System (NPWT)


RENASYS TOUCH


RENASYS EDGE

**TOUCH Quick reference guide**

**EDGE Quick reference guide**

## Description

RENASYS◊ NWPT Systems are engineered to provide NPWT to a closed environment over a wound.

This facilitates the removal of wound exudate, irrigation solutions, body fluids, and infectious materials into a disposable canister, to help promote wound healing.

## Monitoring essentials

### Important information

- Visually check patient, pump, and dressing regularly and per protocol.
- Look for signs of bleeding, exudate accumulation (pooling), infection, maceration, or loss of NPWT.

**Note:** NPWT pumps don't detect or have an alarm for bleeding or pooling.

- Ensure all wound foam/gauze is removed at each dressing change to reduce infection risk.
- Monitor skin grafts to ensure NPWT is being delivered.
- Frequency of checks is determined by clinician, based on patient and wound characteristics.
- Review contraindications, warnings and precautions before use.

### Therapeutic pressure range

- The recommended NPWT pressure range is -40 to -125mmHg.
- The exact setting is determined clinically based on the patient and wound's specific needs.

**Note:** Special attention to the risks of bleeding or loss of NPWT should be considered when prescribing for use in the home environment.

### Patient Size and Weight:

The size and weight of the patient should be considered when prescribing and using the RENASYS NPWT System.

Patients including, infants, children, small stature adults, and elderly patients should be closely monitored for fluid loss and dehydration. Patients with highly exudating wounds or large wounds in relations to the patient size and weight should also be closely monitored due to the risk of excessive fluid loss and dehydration. Monitoring of fluid output should take both the volume of fluid in both the tubing and canister into consideration.

### Key factors for optimization

- System setup and configuration
- Patient and wound specifics (like exudate properties and anatomy)
- Proper alignment of the port with the drape opening, utilizing proper bridging techniques when deemed necessary per clinical assessment, and selecting the appropriate dressing based on wound traits are crucial for maintaining NPWT vacuum efficiency.
- Exudate volume, viscosity, and consistency may affect fluid removal and occlusion formation.
- A full canister, incorrect canister placement, and the relative height of the pump/tubing to the wound may lead to NPWT failure and accumulation of exudate, raising the risk of wound maceration and infection.

### Indications for use

The RENASYS NPWT System is indicated for patients who would benefit from a suction device as it may promote wound healing via removal of fluids, body fluids, wound exudate and infectious materials.

**Note:** When using white foam the density of the material may deliver a reduced level of negative pressure through long sections of the material, for example, tunnels.

### Appropriate wound types:

- Chronic
- Acute
- Traumatic
- Sub-acute and dehisced wounds
- Ulcers (such as pressure or diabetic)
- Flaps and grafts
- Partial thickness burns

## Important information when using the RENASYS◊ AB abdominal kit with Soft Port◊

When used with the RENASYS AB Abdominal Kit with Soft Port, the RENASYS pump is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome. The use of RENASYS AB Abdominal Kit with Soft Port is intended for use in acute hospital care settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating room.

## Contraindications

Do not place NPWT dressings directly in contact with exposed blood vessels, anastomotic sites, organs or nerves.

The use of the RENASYS NPWT System is contraindicated in the presence of:

- Necrotic tissue with eschar

**Note:** After debridement of necrotic tissue and complete removal of eschar RENASYS NPWT System may be used.

- Untreated osteomyelitis
- Malignancy in wound (with exception of palliative care to enhance quality of life)
- Exposed arteries, veins, organs or nerves
- Non-enteric and unexplored fistulas
- Exposed anastomotic sites

## Warnings and precautions

Scan the QR codes below to review warning and precaution information:

**Precautions specific to RENASYS TOUCH**

**Precautions specific to RENASYS EDGE**

## Considerations for device selection

- The RENASYS◊ pumps can be used on a variety of wounds.
- Refer to specific quick reference guides, instructions for use or specific product user manuals for additional instructions.

Please see the appendix for product components and ordering.

### RENASYS TOUCH


### RENASYS EDGE

**Features**

#### Versatility and ease of use

- Intuitive, user-friendly touchscreen
- Small, lightweight, and portable
- Soft-port technology

#### Therapy modes

- Features two therapy modes: continuous and intermittent.
- Intermittent therapy mode provides both intermittent and variable set point options.

#### Device monitoring and operation

- Includes a pump activity log to record pump running time, mode selection, and alarms.
- Equipped with a flow meter providing a visual indication to help determine if there are any leads or if the system is properly sealed.
- Equipped with an informative pump display that includes on-screen help.

#### Running time

- Provides 10-16 hours of therapy when operating at pressures from -25mmHg to -120mmHg.

#### Patient-friendly

- Interface with step-by-step guidance
- On-board troubleshooting and support
- Small, lightweight and portable
- Discreet canister
- Soft-port technology

#### Therapy modes

- Features two therapy modes: continuous and intermittent.

#### Device monitoring and operation

- Includes pump activity log.
- Includes near-field communication technology for instant online support.
- Includes a flow meter.
- Streamlined design – less than a 5-minute cleaning process.

#### Running time

- >24 hours of therapy when operating at -125mmHG

| | RENASYS◊ TOUCH | RENASYS EDGE |
|---|---|---|
| |  |  |
| **Components** | • Pump<br>• Power cord<br>• Single patient use carrying case and strap available<br>• IV Pole/Bed rail clamp available<br><br>**300ml RENASYS TOUCH Canister**<br>• Sealed canister<br>• With or without solidifier<br>• Canister tubing<br>• Kickstand<br><br>**800ml TOUCH Canister**<br>• Sealed canister<br>• With or without solidifier<br>• Canister tubing | • Pump<br>• Power cord<br>• Single patient use carrying case and strap available<br><br>**RENASYS EDGE Canister 300ml**<br>• Sealed canister<br>• With solidifier<br>• Canister tubing |
| **Pump/ canister optimization** | Device and canister should remain in an upright orientation to maximize canister volume and optimize complete blockage/canister over capacity alarm. | Device and canister should remain in an upright orientation to maximize canister volume and optimize complete blockage/canister over capacity alarm. The RENASYS EDGE device should be placed no higher than 19 inches (50cm) above the wound when possible. |

**Caution: Canister kits are single use non-sterile.**

1. Always use the smallest canister volume possible.
2. DO NOT use the 800ml canisters on patients with high risk of bleeding.
   **Note:** 800ml canisters are not available with RENASYS EDGE System.
3. Canisters should be changed at least once a week, whenever there is a change of patient or if the canister contents reach maximum volume indication. Do not wait for canister over-capacity alarm activation to change canister.
4. After two or more 300ml RENASYS EDGE canister changes without the canister full alarm notification, consider switching to the PICO sNPWT System.

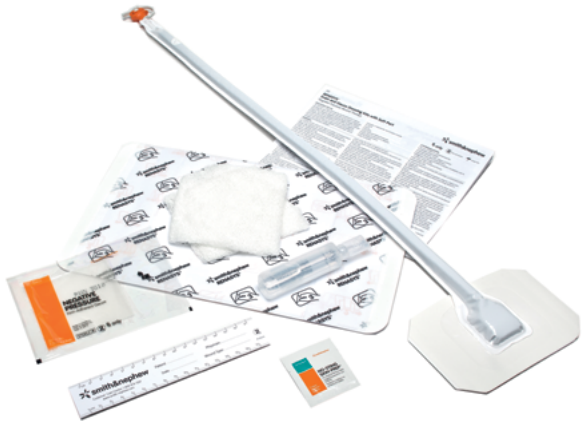
See appendix for product components and ordering.

# General therapeutic considerations

## Choosing a wound filler and interface

Smith+Nephew provides clinicians with various dressing kit options compatible with their RENASYS◊ negative pressure wound therapy (NPWT) Systems, including:

RENASYS foam with Soft Port◊



RENASYS gauze with Soft Port

RENASYS WF white foam

(Dense, open-pore polyvinyl alcohol foam pre-moistened with sterile water)

Abdominal Dressing kit with Soft Port

Clinical studies have shown that gauze and foam dressings yield comparable healing rates, with similar percentages of wound volume or surface area reduction per week. Therefore, healthcare professionals can expect similar results from either type of dressing material.

Guidelines for choosing between RENASYS dressing kit options have been formulated from the feedback and experiences of healthcare professionals who have utilized the full range of available kits.

## Dressing changes

Consult the RENASYS◊ dressing kits' instructions for further details on dressing application and care.

1. Change foam dressings every 48 to 72 hours or at least three times weekly if there are no leaks and the patient is comfortable.
2. Replace gauze dressings 48 hours after starting therapy, adjusting to 2–3 times weekly based on patient comfort and absence of leaks.
3. Increase monitoring and frequency of dressings changes if the drainage has sediment or blood present or if it is heavy or viscous.
4. For wounds with complex anatomy or risk of moisture exposure, inspect dressings regularly to maintain a seal, ensuring they are compressed and firm.
5. Before re-dressing, ensure all filler material is removed. If the foam sticks to the wound, moisten with saline for 15–30 minutes before gently removing it. Dispose of dressings according to your institution's medical waste protocols.
6. Apply and remove dressings gently on sensitive or fragile skin to prevent skin stripping. Use of skin sealant may assist with protection of periwound skin.
7. Watch for signs of local or systemic infection, which may require more regular changes. Alert the treating clinician if systemic or advancing local infections are detected.
8. If the RENASYS pump signals a blockage, check and clear the dressing and canister tubing. If unresolved, replace the canister first, then remove the dressing and Soft Port and replace if needed.

## General guidelines:

The guidelines on therapy settings in this booklet are general recommendations. You may wish to vary the pressure settings to optimize NPWT therapy based on the treatment goals for the patient and clinical judgment.

**Note:** Recommended pressure range for the RENASYS NPWT Systems is -40mmHg to -125mmHg.

- If a patient experiences discomfort, it may help to reduce the pressure level.
- An increase in the pressure may be necessary according to size of wound, viscosity of exudate, amount of exudate and clinical judgment of desired wound outcomes.
- Anatomical location and tissue pliability may also influence pressure level utilized.
- If the patient is experiencing pain with the intermittent mode, consider switching to variable intermittent NPWT.

NPWT should remain on for duration of treatment. If patient must be disconnected from the pump, the ends of the Soft Port and canister tubing should be protected using tethered caps.

**The length of time a patient may be disconnected from the pump is a clinical decision based on individual characteristics of patient and wound.**

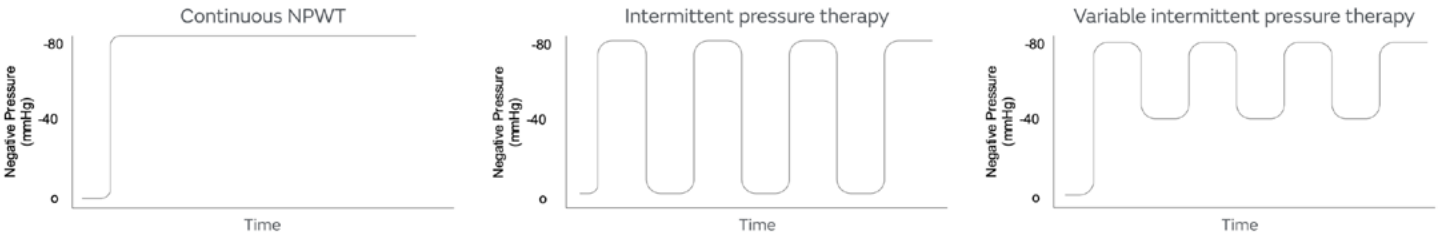
## Overview of NPWT modes

### NPWT can be delivered to the wound bed using three modes of delivery

- **Continuous:** Pressure is applied constantly.
- **Intermittent:** Pressure is repeatedly switched on and off alternating between 0 and set pressure.

**Note:** The lowest pressure setting for the intermittent therapy mode on RENASYS◊ EDGE is -25mmHg where as for RENASYS TOUCH is 0mmHg.

- **Variable intermittent mode:** Pressure is varied between two levels (set pressure and low pressure) maintaining a negative pressure environment throughout the therapy.




## Continuous versus intermittent therapy

An additional aspect of pressure setting is the choice between continuous, intermittent, and variable intermittent. The RENASYS TOUCH and EDGE devices offer variable maximum and minimum pressures and times. The NPWT setting should be determined by prescribing clinician and tailored to the individual wound for optimal effects.

## Considerations for use of intermittent or variable intermittent therapy

- It is recommended that all patients remain on continuous therapy for the first 48 hours.
- Intermittent therapy is not recommended for:
  - Highly exudating wounds
  - Wounds with tunnels or undermining
  - Wounds in difficult areas where maintaining a seal is problematic

During the off period, if the wound has large volumes of exudate, there may be a tendency for exudate to leak out and break the adhesive film seal.

**Note:** Most effective delivery of variable pressure is thought to occur when pressure cycles between a 'high' level of pressure within the therapeutic range of -40mmHg to -125mmHg to a 'low' pressure of below the therapeutic range of NPWT (i.e. below -40mmHg).[21]

## Consideration for use of continuous therapy

**Note:** In patients who would benefit from intermittent therapy but who experience wound pain, please select the variable intermittent therapy option.

**Note:** Pain during the application of NPWT may be experienced more frequently during the on and off cycle of intermittent therapy. Less pain is experienced with variable intermittent therapy.[22]

- Continuous therapy is generally recommended for the first 48 hours, with patients at increased risk of bleeding, highly exudating wounds, fresh flaps and grafts, and wounds with acute enteric fistula.
- Continuous therapy is also recommended in wounds with tunneling and undermining.

**Note:** The RENASYS TOUCH and EDGE devices can deliver intermittent and variable intermittent NPWT using tailored time settings defined by the clinician and within the permitted device High and Low duration and pressure levels as outlined below.

## RENASYS◊ TOUCH Therapy Settings

**Continuous therapy levels**
25, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200mmHg

**Intermittent therapy levels**
High: 25, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180, 200mmHg

Low: 0, 25, 40, 50, 60, 70, 80, 90, 100, 120, 140, 160, 180mmHg

**Intermittent therapy cycle times**
High: 3, 5, 8, 10 minutes

Low: 2, 3, 5, 8, 10 minutes

## RENASYS EDGE Therapy Settings

**Continuous therapy levels**
25, 40, 60, 80, 100, 125, 150, 175, 200mmHg

**Intermittent therapy levels**
High: 40, 60, 80, 100, 125, 150, 175, 200mmHg

Low: 25, 40, 50mmHg

**Intermittent therapy cycles times**
High: 5, 8, 10 minutes

Low: 2, 3, 5 minutes

Experimental studies have shown improvements in the rate of granulation tissue formation, wound contraction and blood flow with intermittent and variable NPWT compared with continuous NPWT.[22]

The choice to use continuous or intermittent therapy should be based on clinical judgment and the therapy objective of the wound being treated.

## Delivering the right pressure level

With respect to pressure levels, an independent International NPWT Expert Panel convened to develop evidence-based recommendations describing the use of NPWT.[5]

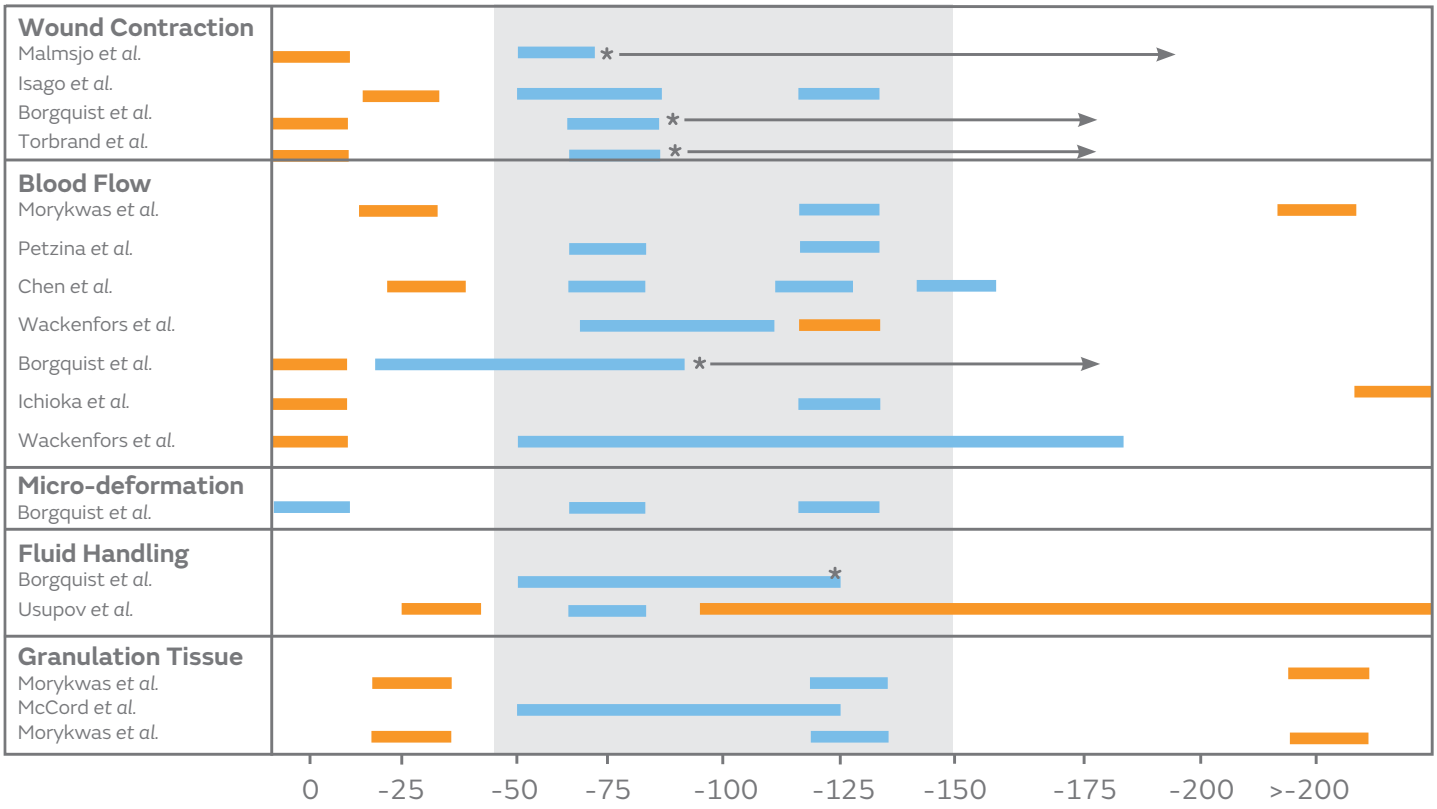
They recommended that NPWT be used within a therapeutic range of -40mmHg to -125mmHg. The recommended pressure settings for RENASYS NPWT devices fall within this range.[5]

## Recommendations for pressure settings and filler depending on wound type

The guidelines on therapy settings are general recommendations. You may wish to vary the pressure settings to optimize NPWT therapy based on individual patient need and the lead clinician's guidance.

| Wound type | | Suggested filler | Pressure setting | Wound contact layer | Special considerations |
|---|---|---|---|---|---|
| **Acute/traumatic** | | Gauze or foam | -80 to -120mmHg | If tendon, bone, and/or other fragile structures are exposed | Infected wounds and fragile structures should be protected and care taken to avoid desiccation of tendon if exposed |
| **Partial thickness abdominal (muscle intact)** | | Foam | -80 to -120mmHg | Not required unless adhesion occurs | Layer the filler into the wound to ensure it fits the cavity from the bottom up to ensure contact with the wound margins |
| **Full thickness abdominal (muscle intact)** | Decompression & closure | Abdominal dressing with OPL | -60 to -120mmHg | OPL large enough to cover all fragile structures should be used | The lead clinician must take full responsibility for treatment choices and materials/method of NPWT and pressure setting used |
| | Healing by secondary intention | Gauze | -60 to -120mmHg | Essential to protect exposed fragile structures | Use a single layer of wound contact layer to ensure any fragile structures are protected and to ensure it is removed and replaced at each dressing change. Extra care should be taken when patients have inflammatory bowel disorders/infected/inflamed bowel. Lead clinician must be consulted prior to commencement of therapy |
| **Pressure injuries** | | Gauze | -60 to -80mmHg | Yes if tendon/bone exposed | Always address underlying aetiology and factors affecting healing – if slough or necrosis present debride prior to commencement of NPWT or consider using foam |
| **Diabetic foot ulcers post surgery** | | Gauze | -60 to -80mmHg | Yes if tendon/bone exposed | Dressing should be placed as soon after surgery as is practical once hemostasis is achieved |
| **Diabetic foot ulcers** | | Gauze or foam | -60 to -80mmHg | Yes if tendon/bone exposed | Sharp debridement of any devitalized tissue should occur prior to placement of NPWT |
| **Meshed grafts/bioengineered tissue** | | Gauze | -50 to -80mmHg | Yes to avoid adherence of filler to the graft | Dressings are typically removed after 5 days or as per clinician instructions |
| **Flaps** | | Gauze | -50 to -80mmHg | Yes to avoid adherence of filler to the graft | Dressings are typically removed after 5 days or as per clinician instructions |
| **Dehisced surgical wounds** | | Foam | -80 to -120mmHg | Yes if tendon, bone, and/or other fragile structures are exposed | Consideration should be taken to debride any devitalized tissue prior to commencement of NPWT |
| **Chronic wounds** | | Gauze | -80mmHg | Yes if tendon/bone exposed | Always address underlying etiology and factors affecting healing |
| **Enteric fistula (explored)** | | Gauze or foam | -80mmHg | Yes to protect exposed fragile structures | See RENASYS High Output Dressing Kit application technique on page 53 |

## Recommended pressure settings for RENASYS◊ NPWT devices[5]




* Although higher levels of negative pressure may be effective (denoted by arrows), no further benefit observed.

## Impact of varying negative pressure on mode of action of NPWT[5]

- **Orange bars** indicate pressure where no effect or detrimental effects have been observed.
- **Blue bars** indicate where beneficial effects have been observed.
- **The shaded area** demonstrates the therapeutic range of negative pressure levels based on most studies. Studies on intact volunteer skin excluded.

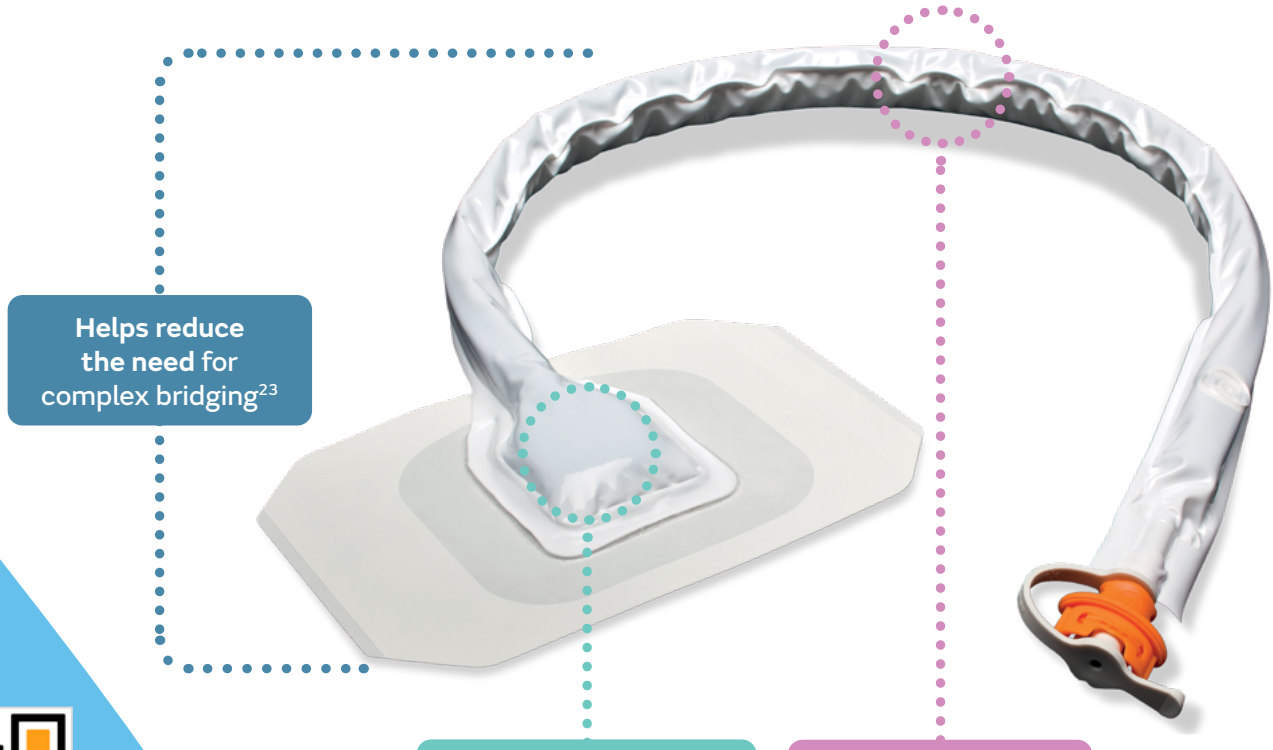
## Dressing selection and guidance

Our RENASYS◊ Soft Port◊ replaces traditional plastic tubing with a soft, comfortable, compression resistant alternative.[23–25] Use our Soft Port to ensure the chosen vacuum is delivered to the wound. The flexibility and adaptability of RENASYS Soft Port can improve the quality of your wound care.

RENASYS Soft Port is used with both foam and gauze dressings.

### RENASYS Soft Port: Considerations for use

- It is important to align the opening of the Soft Port with the cut hole in the transparent film to ensure a good seal and decrease the risk for a false blockage alarm.
- The Soft Port opening is 1.5cm in diameter. It is important that the cut hole in the transparent film is no less than 2cm in diameter.
- When cutting the hole in the transparent film remove any loose edges from the film to prevent aspiration into the Soft Port, possibly causing a false blockage alarm.
- Under normal circumstances, it should not be necessary to bridge away from the wound. If there is a concern that the Soft Port may create pressure at the wound, due to the wound's location and condition, or if the wound is smaller than the Soft Port opening (1.5cm), utilize the bridge technique on page 47.



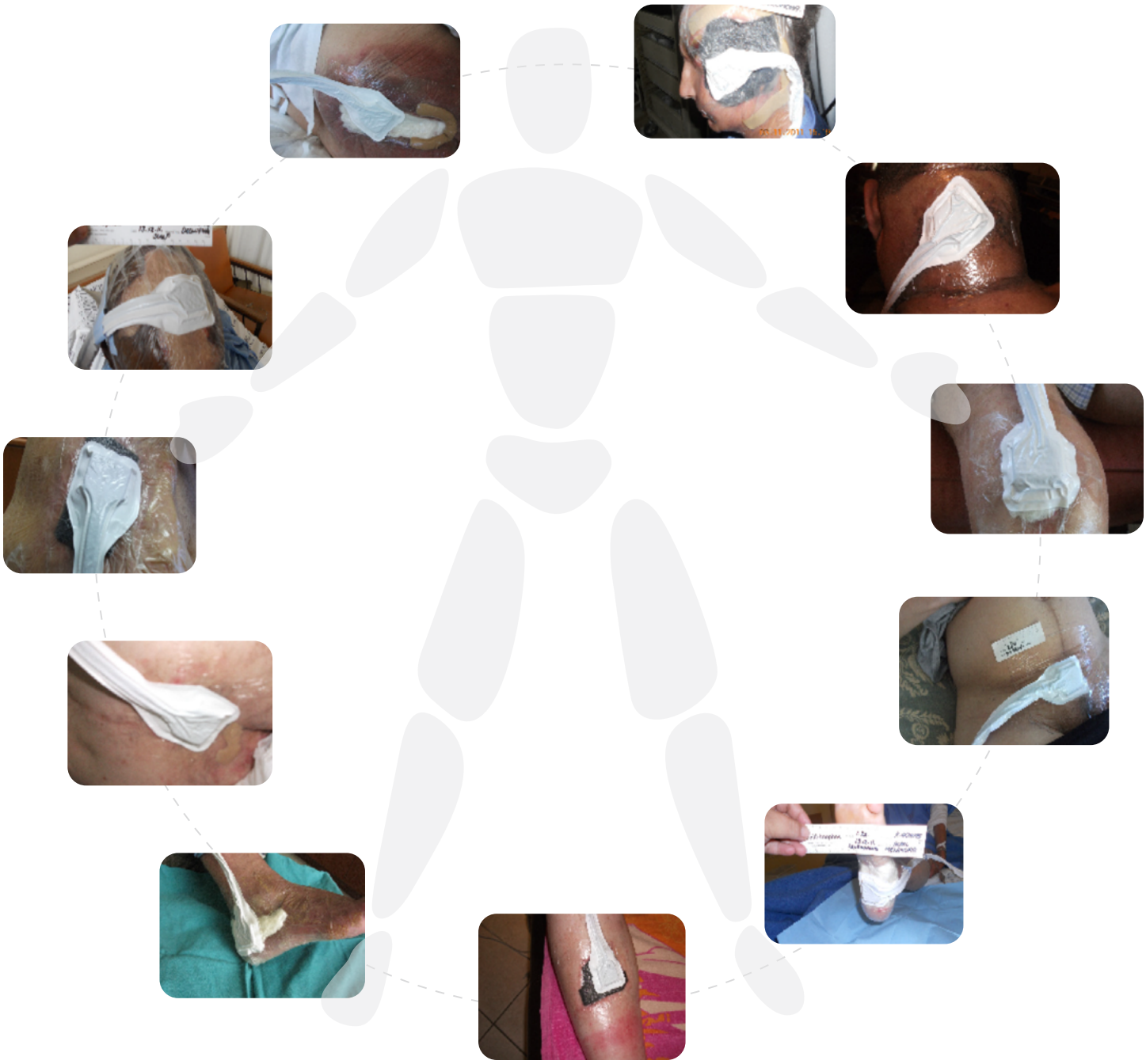

**Soft Port information**

## Considerations when ordering NPWT

Prior to placement of the RENASYS◊ device, the healthcare professional treating the wound must assess how best to use the system for an individual wound. It is important to carefully assess the wound and the patient to ensure clinical indications for NPWT are met.

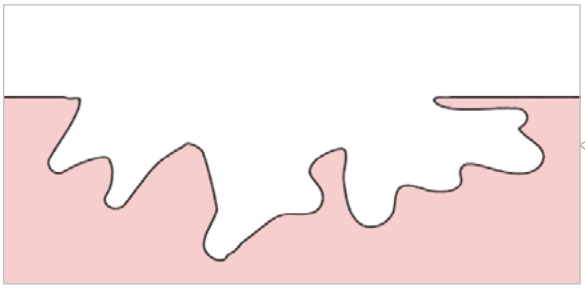
### All treatment orders should include:

- Size and/or wound measurements
- Smith+Nephew wound dressing kit type
- Vacuum settings (recommended therapeutic range is -40 to -125mmHg)
- Frequency of dressing changes
- Adjunctive dressings

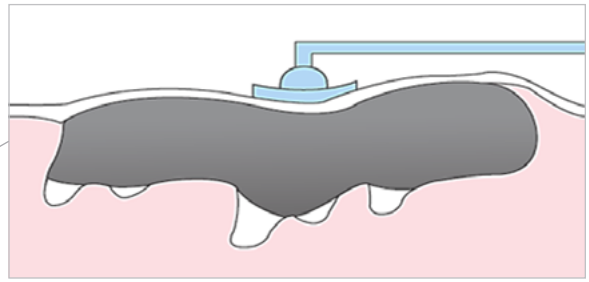


# Choosing a wound dressing: 3 key factors to consider

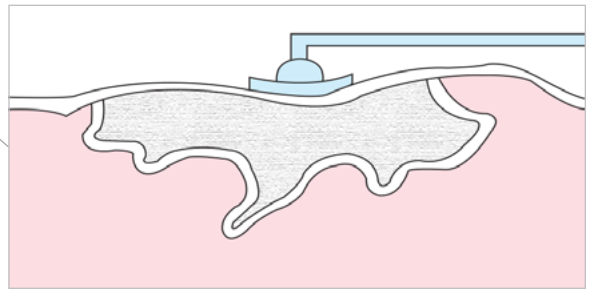
## 1. Wound irregularity



Wound bed with irregular contour

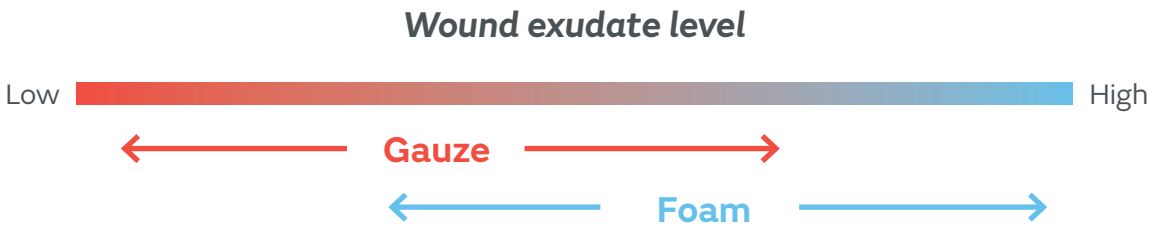


**Foam wound filler** may not intimately contact irregular shape spaces in wound bed

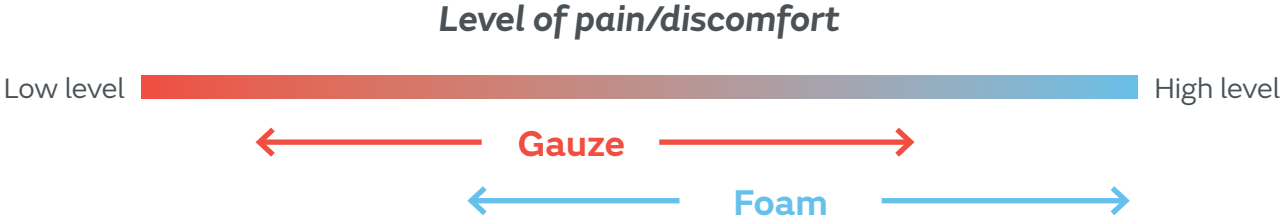


**Gauze wound filler** easily maintains contact with irregular surface

## 2. The amount and consistency of wound exudate



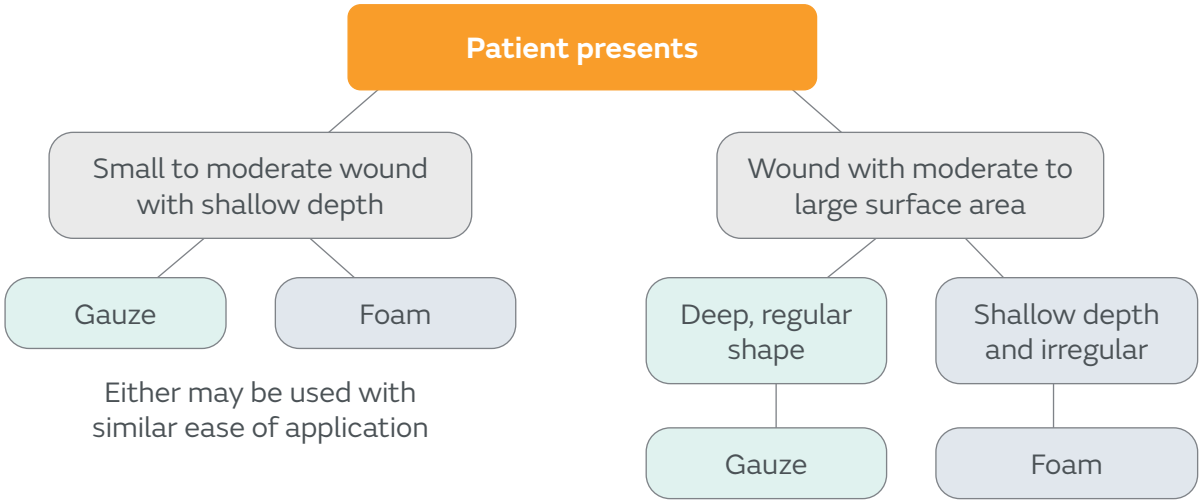

## 3. Patient comfort - the amount of pain a patient experiences during NPWT and dressing changes



## RENASYS◊ Dressing Kit options

| Wound characteristics | White Foam with Soft Port◊ | Foam with Soft Port | Gauze with Soft Port |
|---|---|---|---|
| Large wound with regular contours | | ✔ | |
| Presence of undermining | ✔ | ✔ | ✔ |
| Patient has pain on dressing removal | ✔ | | ✔ |
| Weight bearing area | | ✔ | |
| Heavy exudate levels | | ✔ | |
| Moderate exudate levels | | ✔ | ✔ |
| Viscous exudate | | ✔ | |
| Serous exudate | | ✔ | ✔ |
| Statis chronic wound | | ✔ | |
| Skin grafts | ✔ | ✔ | ✔ |
| Sinus wound or wound with narrow opening | ✔ | | ✔ |
| Combination wounds cavity plus sinus (See advanced dressing applications, page 44) | ✔ | ✔ | ✔ |

## How to choose the optimal filler option based on wound size and volume[19]




## Precautions specific to gauze

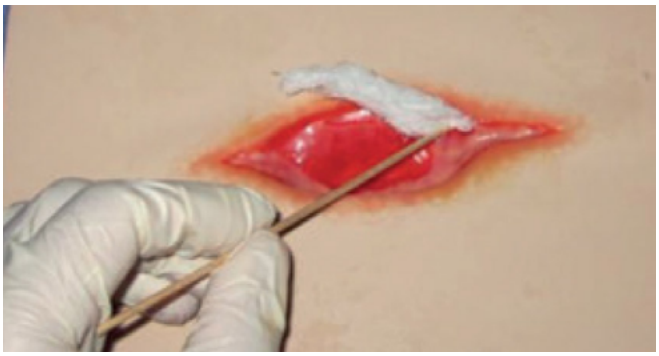
1. Use of gauze as a filler in wounds that are in a weight bearing location or have moderate to heavy drainage may challenge the transfer of fluid and vacuum. Foam is recommended in these wounds. RENASYS◊ foam and gauze filler may be combined within the same wound when tunneling or undermining is present.
2. Gauze may be used in the areas of undermining or tunneling, with foam placed in the remainder of the wound cavity. In wounds with large amounts of exudate a wound interface (non-adherent layer) is generally not recommended.

## Gauze/foam combination therapy

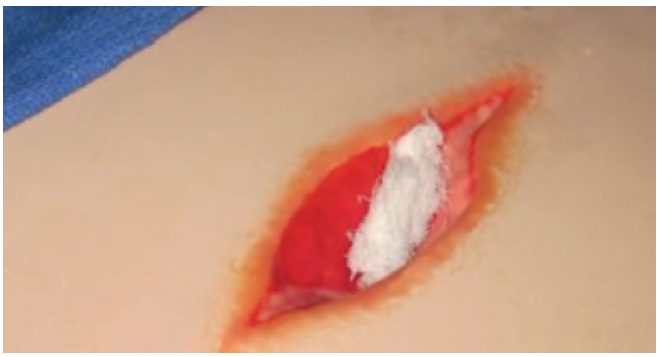
- RENASYS foam and gauze filler may be combined within the same wound when tunneling or undermining is present.
- Gauze may be used in the areas of undermining or tunneling, with foam placed in the remainder of the wound cavity.
- When using RENASYS white foam, due to the higher density of white foam, a reduced level of negative pressure may be delivered through long sections of the foam.

## Step-by-step process for combination use

1. When using gauze in a tunnel or undermining area, ensure a tail is exposed for ease of removal and/or sufficient contact with the foam layer.

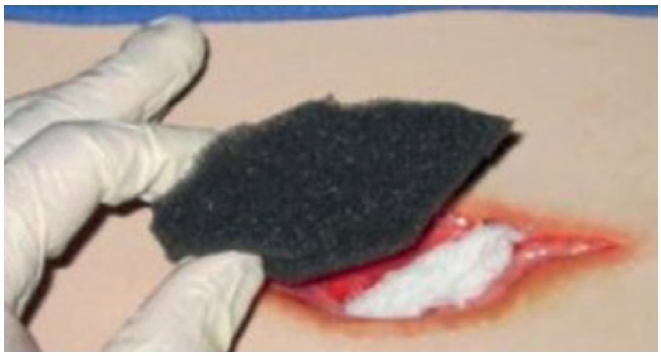


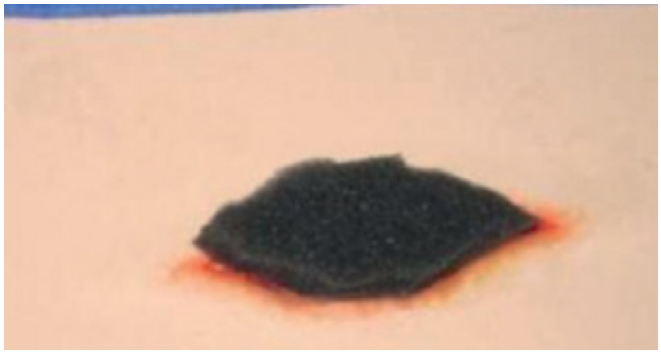
2. Visual representation of gauze placed into undermined area.



3. Visual representation of the foam/gauze combination outside the wound.

4. When using gauze in a tunnel or undermining area, ensure a tail is exposed for ease of removal and/or sufficient contact with the foam layer.





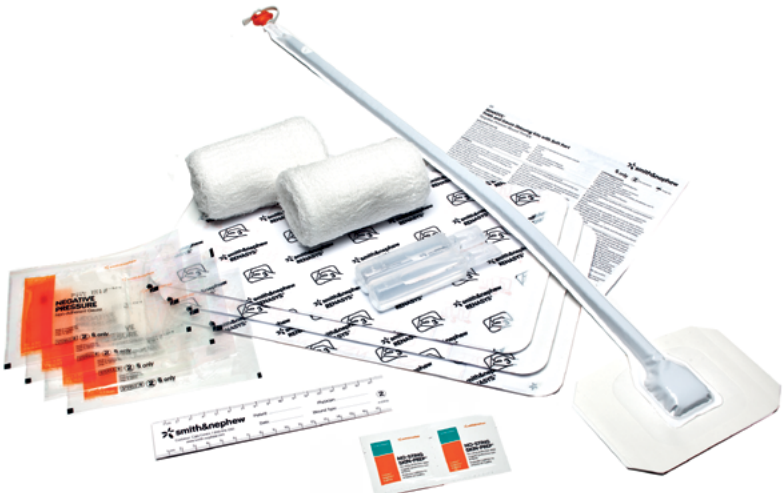
**Note:** Count and document the number of pieces of each material to ensure complete removal of the filler when the dressing is changed.

**Note:** Contact must be maintained between the two materials.

**Caution:** Infected wounds may require more frequent dressing changes. Regular monitoring of the wound should be maintained to check for signs of infection.

# Dressing selection and application: Gauze

## RENASYS◊-G Gauze Dressing with Soft Port◊ application technique



- Refer to the RENASYS-G gauze dressing kit Instructions for Use leaflet for further information.
- Use clean or sterile/aseptic techniques protocol. Only use RENASYS dressing kits that are approved for use with the RENASYS System.
- See page 92 of the appendix for kit sizes and components.

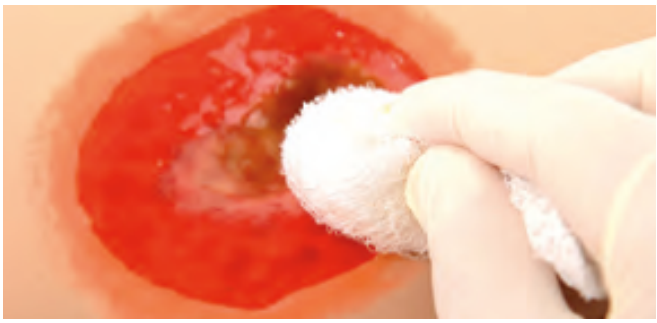
## Considerations specific to gauze

1. Use of gauze as a filler in wounds that are in a weight bearing location or have moderate to heavy drainage may challenge the transfer of fluid and vacuum. Foam is recommended in these wounds.
2. RENASYS foam and gauze filler may be combined within the same wound when tunneling or undermining is present. Gauze may be used in the areas of undermining or tunneling, with foam placed in the remainder of the wound cavity.

**Gauze application video**

## Step 1
## Clean and debride

1. Debride any devitalized or necrotic eschar tissue.
2. Cleanse the wound and pat dry.

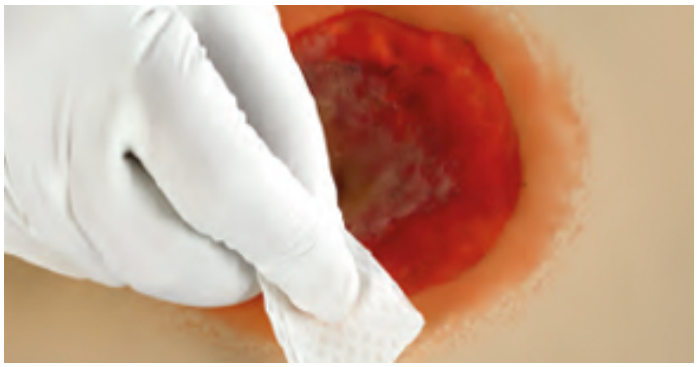


**Note:**

- Use clean or aseptic techniques for application, according to your institutional protocol.
- Thorough wound cleansing should occur with each dressing change.

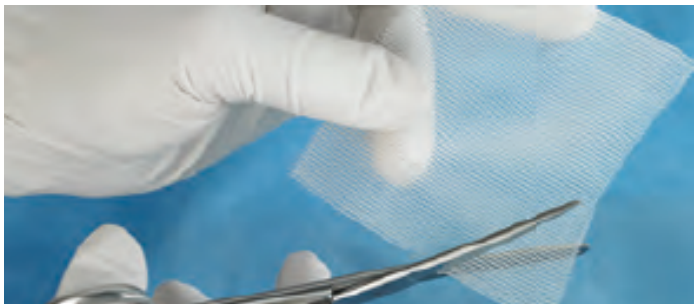
**Optional:**

- Use a skin sealant to protect the peri wound skin.
- Allow the skin sealant to dry fully prior to placement of the transparent film.



**Optional:**

- Apply a non-adherent dressing.



## Step 2
## Dress wound with gauze

1. Apply a layer of saline-moistened antimicrobial gauze to wound bed.

2. Unfold remaining saline-moistened gauze and loosely fill the entire wound cavity.

**Caution:** If multiple pieces of wound filler are needed to fill the wound profile, count and record how many pieces are present to ensure all wound filler pieces are removed at a dressing change to minimize the risk of retention and possible infection.

## Step 3
### Seal the wound

1. While holding the transparent film, expose one side of the adhesive backing by removing a single panel and apply over the wound.


2. Cover the wound filler with transparent film, removing remaining adhesive panels to seal, the top stabilization panel.

**Recommendations:**

- Film should extend at least 5cm/1.97in beyond wound margin and be securely anchored to periwound area to maintain a good seal.
- Overlap the edges of the transparent film by a minimum of 7.5cm/2.95in when using multiple pieces of transparent film.

**Note:** Avoid stretching or pulling the transparent film to minimize tension or trauma to the periwound skin.

## Step 4
### Apply a RENASYS◊ Soft Port◊

1. Cut a circular opening (no less than 1in in diameter) in the center of the film, over the wound filler.
2. Remove any loose transparent film and dispose of away from the wound.

3. Remove the adhesive panel from the RENASYS Soft Port dressing and align the port opening directly over the hole in the transparent film.

4. Align the Soft Port opening directly over the hole in the transparent film. Use gentle pressure to anchor the Soft Port to the transparent film.

5. Smooth the dressing down while removing the RENASYS Soft Port top stabilization frame.

6. Secure the RENASYS Soft Port to the patient according to your institutional protocol.

**Note:** Ensure the aeration disc, located near the quick click connector, is not covered or otherwise occluded by the method used to secure the Soft Port.

7. Connect the RENASYS Soft Port to the canister tubing by pushing the quick click connectors together.

8. Turn on the RENASYS pump, adjust the pump to the prescribed therapy level and then activate the RENASYS pump.


9. Finished dressing should be firm to the touch and leak free.

# Dressing selection and application: Foam

## RENASYS◊-F Foam Dressing with Soft Port◊ application technique

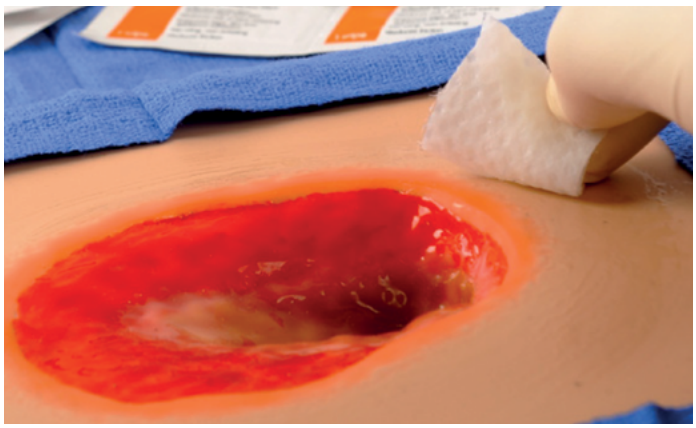
- Refer to the RENASYS-F Foam Dressing kit Instructions for Use leaflet for further information.
- Use clean or sterile/aseptic techniques protocol. Only use RENASYS dressing kits approved for use with the RENASYS System.
- See page 92 of the appendix for kits sizes and components

### Step 1

## Clean and debride

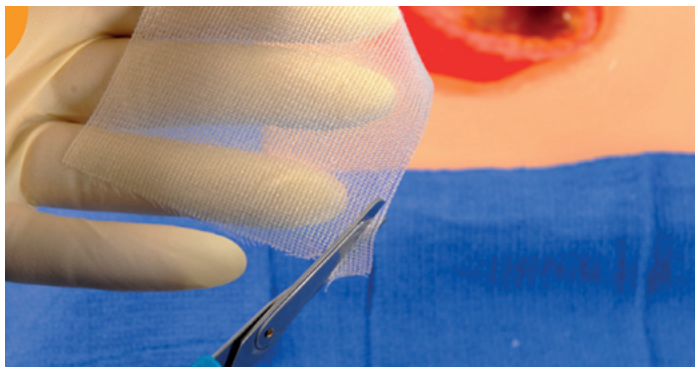
1. Debride any devitalized or necrotic eschar tissue.
2. Cleanse the wound bed and pat dry.

**Optional:**



- Use a skin sealant to protect the peri wound skin.
- Allow the skin sealant to dry fully prior to placement of the transparent film.

**Optional:**



- Apply a non-adherent dressing

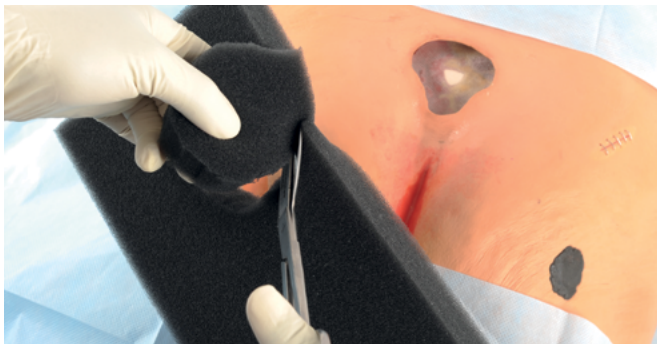
**Note:**

- Use clean or aseptic techniques for application, according to your institutional protocol.
- Thorough wound cleansing should occur with each dressing change.

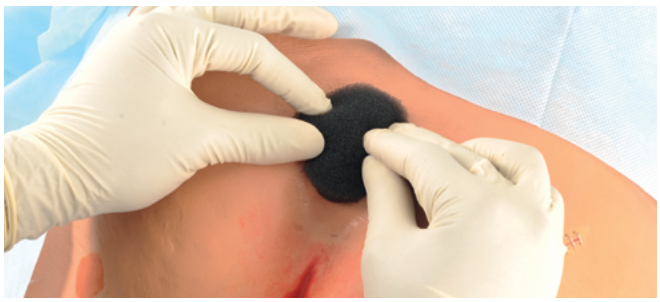
### Step 2

## Dress wound with foam

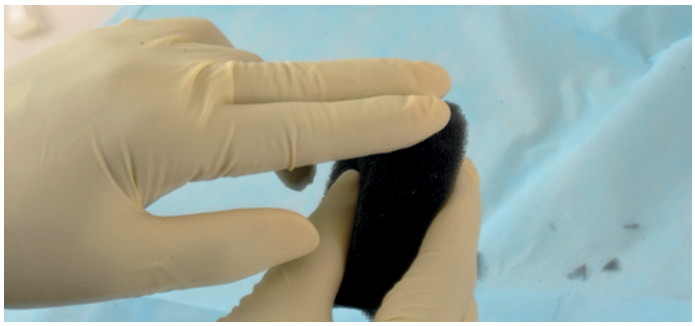
1. Cut the foam dressing to fit the size and shape of the wound and place the cut foam into the wound.



2. Avoid overpacking. Foam should completely fill the wound cavity. It may be necessary to stack pieces of foam in deep wounds.



**Caution:** If multiple pieces of wound filler are needed to fill the wound profile, count and record how many pieces are present to ensure all wound filler pieces are removed at a dressing change to minimize the risk of retention and possible infection.



## Step 3
## Seal the wound

1. Remove panel #1 of the Transparent Film, exposing the adhesive. Apply over the wound and remove the remaining panel #2 to seal. Once placed, remove the top panel #3. Continue to apply until the foam is completely covered and the wound is sealed.

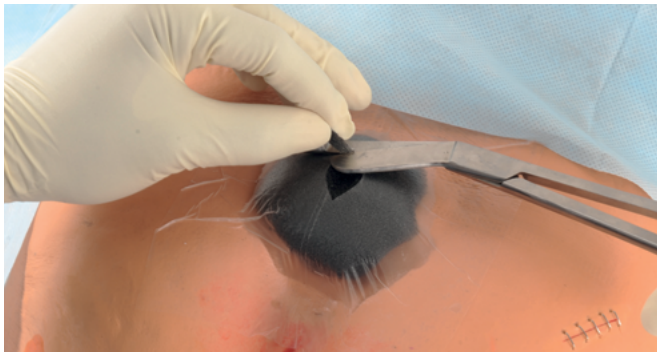
## Recommendations:

- Film should extend at least 2-3in beyond wound margin and be securely anchored to periwound area to maintain a good seal.
- Overlap the edges of the transparent film by a minimum of 7.5cm/2.95in when using multiple pieces of transparent film.

**Note:** Avoid stretching or pulling the transparent film to minimize tension or trauma to the periwound skin.

## Step 4
## Apply a RENASYS◊ Soft Port◊

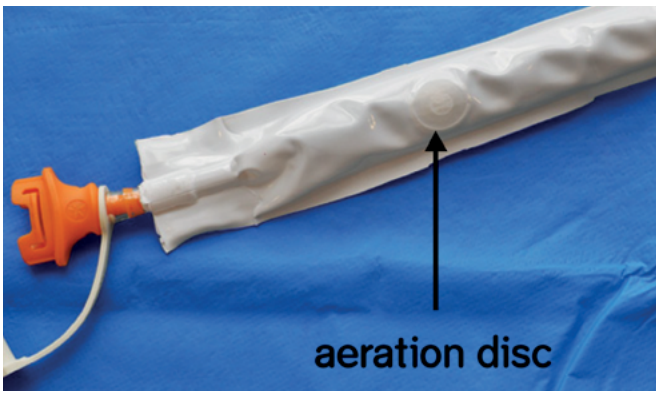
1. Cut a circular opening (no less than 1" in diameter) in the center of the film, over the wound filler.



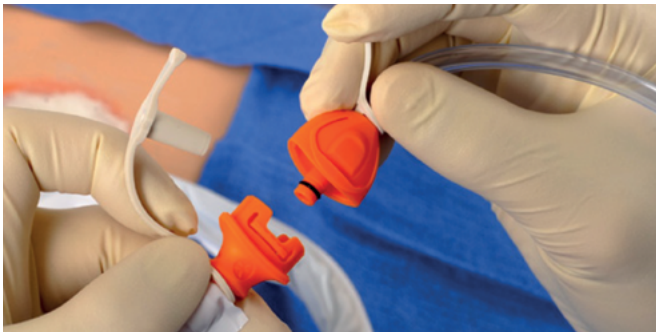
2. Remove any loose transparent film and dispose of away from the wound.
3. Remove the adhesive panel from the RENASYS Soft Port dressing and align the port opening directly over the hole in the transparent film.

4. Align the Soft Port opening directly over the hole in the transparent film. Use gentle pressure to anchor the Soft Port to the transparent film.
5. Smooth the dressing down while removing the RENASYS Soft Port top stabilization frame.

6. Secure the RENASYS Soft Port to the patient according to your institutional protocol.
7. Ensure the aeration disc, located near the quick click connector, is not covered or otherwise occluded by the method used to secure the Soft Port.




8. Connect the RENASYS Soft Port to the canister tubing by pushing the quick click connectors together.



9. Turn on the RENASYS◊ pump, adjust the pump to the prescribed therapy level and then activate the RENASYS pump.


10. Finished dressing should be firm to the touch and leak free.

## How to enhance dressing wear time

- Ensure that intact skin is dry prior to applying adhesive dressing.
- Skin sealant such as NO STING SKIN-PREP◊ should be routinely used to protect the periwound area. Allow to fully dry prior to applying film dressing.
- If skin in the periwound area is damaged or fragile, a hydrocolloid or adhesive film may be used to protect the area prior to applying the cover transparent film.
- Apply skin sealant such as NO STING SKIN-PREP barrier over the edges of transparent film to prevent rolling.
- Apply the RENASYS◊ Adhesive Gel Patch and/or Ostomy Strip Paste to skin irregularities such as abdominal skin folds or cleft at sacrococcygeal junction. This will help to decrease depth of the skin irregularity. See RENASYS Accessory - Gel Patch section for more information on application technique.
- Film should extend at least 2in beyond wound margin and be securely anchored to periwound area to maintain a good seal.
- Overlap the edges of the transparent film by a minimum of 3in when using multiple pieces of transparent film.
- If it is necessary to add more foam or gauze to the wound after dressing application, the clinician may create an opening in the film, apply filler, and reseal the dressing as indicated. It is not necessary to restart dressing application.
- It is important to secure the tubing to the patient using extra film or tape to prevent pulling on the dressing which may compromise the dressing seal.
- Do NOT tape over aeration disc to secure tubing. Must secure above or below disc.
- When a leak is identified or located, utilize film dressing to patch the areas without having to replace the dressing.
- If skin irritation is noted underneath the film dressing, discontinue therapy and notify prescribing physician or clinician.
- It is important when applying the film dressing not to pull tightly or stretch the film to avoid trauma to surrounding skin.

# Dressing selection and application: White Foam

## White foam with Soft Port◊ application technique

White foam negative pressure wound therapy (NPWT) dressing is a moist, sterile, polyvinyl alcohol (PVA) foam intended for use in the management of wounds via the application of NPWT when used in conjunction with a Smith+Nephew RENASYS System.

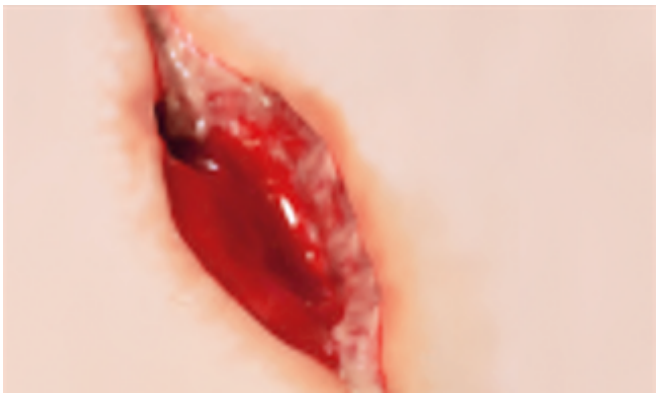
The use of white foam may be deemed suitable if the stimulation of granulation tissue in the wound is to be restricted or a less adherent dressing is required. Due to the higher density of white foam, a reduced level of negative pressure may be delivered through long sections of the foam.

**Foam application video**

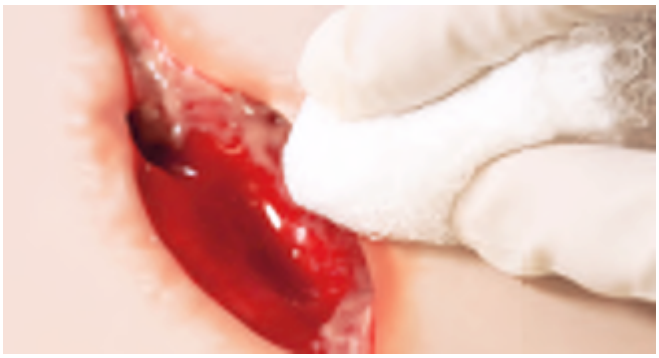
Step 1

## Assess, cleanse and debride the wound

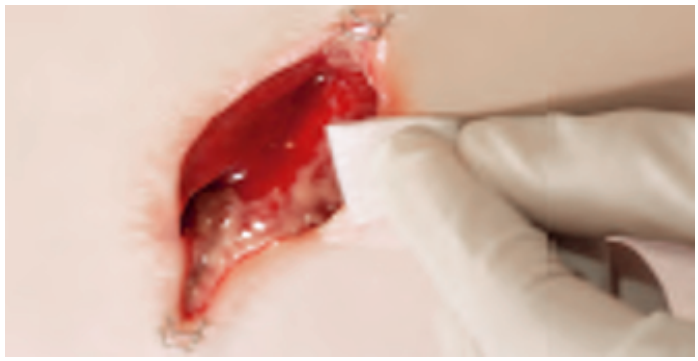
1. Assess the wound dimensions and characteristics, including size and shape, wound exudate levels, any undermining/ tunneling, the presence of any veins, arteries, organs, tendons, ligaments or nerves and osteomyelitis.



2. Cleanse the wound bed according to your institutional protocol.



## Optional:



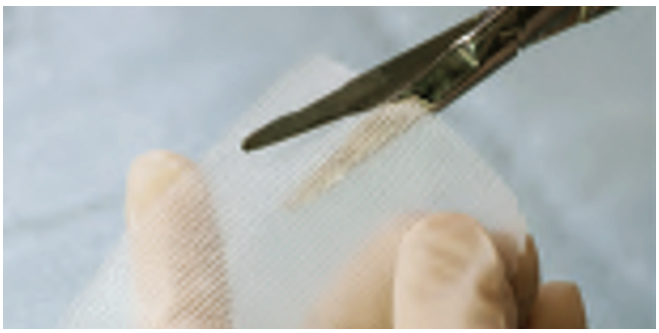
- Use a skin sealant to protect the peri wound skin.
- Allow the skin sealant to dry fully prior to placement of the transparent film.

**Note:**

- Use clean or aseptic techniques for application, according to your institutional protocol.
- Thorough wound cleansing should occur with each dressing change.

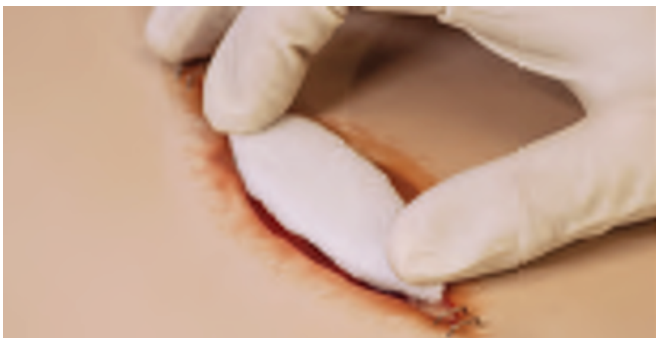
## Step 2
## Dress wound

1. Ensure that all exposed bone, tendons and ligaments in/around the wound are completely covered and protected by either a layer of viable natural tissue or by a nonadherent wound contact layer prior to application of white foam.
   – If using in an explored tunneling wound, ensure the white foam is longer than the tunnel and wedge shaped to assist easy removal.



2. Cut white foam to fit the size and shape of the wound. Do not cut white foam over the wound.

3. Gently place white foam into the wound. Make sure the white foam does not cover the skin around the wound or growing epithelium at the wound edge.



4. Count number of pieces used in the wound.
5. If it is necessary to stack pieces in deep wounds, RENASYS◊-F or RENASYS-G should be placed over white foam to fill the remainder of the cavity, allowing for optimal pressure distribution. Use RENASYS foam or RENASYS gauze according to the instructions for use provided
6. If multiple pieces are needed to fill the wound profile, count and record how many pieces are used to ensure all pieces are removed at a dressing change to minimize the risk of retention and possible infection.

**Note:** Do not cut white foam over the wound, as fragments may fall into the wound bed. Always rub the cut white foam away from the wound bed to remove loose edges.

Avoid overpacking or forcing the dressing into the wound. Do not stack or overlap more than 2 layers of white foam.

**Caution:** If multiple pieces of wound filler are needed to fill the wound profile, count and record how many pieces are present to ensure all wound filler pieces are removed at a dressing change to minimize the risk of retention and possible infection.

## Step 3
## Seal the wound

1. Cut the RENASYS◊ Transparent Film to cover the dressing and a minimum 5cm/2in border to intact periwound skin. If the wound is larger than 1 transparent film, overlap multiple transparent films, ensuring a minimum 7.5cm/3in overlap of film.

2. While holding the transparent film, expose the side of the adhesive backing by removing a single panel and apply over the wound.

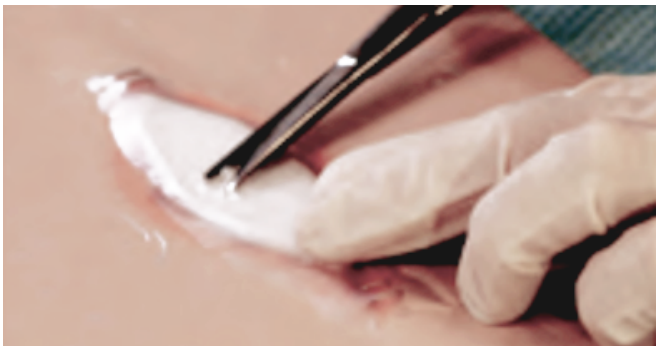
3. Cover wound dressing with transparent film, removing the remaining adhesive panels to seal and then remove the top stabilization panel.

**Note:** Smith+Nephew RENASYS transparent film must be used to seal the wound.

## Step 4

## Apply a RENASYS◊ Soft Port◊

1. Pinch transparent film in the center over the wound dressing and cut a small hole (larger than 2cm/0.79in) in the film. Remove any loose film from the wound area and dispose.



2. Align the port opening directly over the hole in the transparent film and remove the paper handle from the Soft Port dressing.

3. Using gentle pressure, anchor the Soft Port to the transparent film.
4. Smooth the Soft Port dressing down and remove the top paper stabilization frame.
5. Secure the Soft Port to the patient according to your institutional protocol.
6. Connect the Soft Port to the RENASYS device canister tubing by pushing the quick click connectors together. An audible click indicates the connection is secure.

7. Activate RENASYS device and adjust to the prescribed therapy level. Finished dressings should be fully compressed, firm to the touch and leak-free.


**Note:** A Smith+Nephew RENASYS Soft Port must be used to connect the wound to a RENASYS device.

## Dressing changes

- White foam should be changed every 48–72 hours after the initial application of therapy. If no leak is present and the patient is comfortable, dressing changes should occur no less than 3 times per week.
- In the event of heavy or viscous drainage, drainage with sediment, or when blood is present, regular monitoring and more frequent dressing changes may be required.
- When dressing a wound involving difficult to seal anatomy or exposure to external moisture, frequent inspection of the dressing is recommended to ensure a seal is maintained.
- If dressing adheres to the wound, apply normal saline or sterile water into the wound dressing and wait for 15–30 minutes before gently removing the foam. Appropriately discard used wound dressings observing your institution's protocol for medical waste handling.
- As with all adhesive products apply and remove the dressing carefully from sensitive or fragile skin to avoid skin stripping, especially after frequent dressing changes. Use of a skin sealant may assist with protection of periwound skin.
- Monitor patient for any signs of local or systemic infection. Infected wounds may require more frequent dressing changes. If there are any signs of systemic infection or advancing infection at wound area, contact treating clinician immediately and consider discontinuing therapy.
- If the RENASYS◊ device activates a complete blockage alarm, inspect the dressing and canister tubing for any blockages.
- If a blockage cannot be identified or resolved, replace the device canister first, then reassess the dressing and Soft Port◊, replacing as necessary.

## Dressing Removal

1. Turn off the RENASYS device.
2. Disconnect the canister tubing from the Soft Port by applying gentle pressure to the canister quick click connector and then pulling the connectors apart.
3. Close the tethered caps of both quick click connectors to prevent leakage.
4. Remove Soft Port and transparent film from the wound and dispose of.
5. Remove all wound dressing, ensuring all pieces are removed and disposed of. The recommended therapeutic pressure range is -40 to -125mmHg.

# RENASYS◊ Soft Port◊: considerations for use

- Each RENASYS Dressing Kit with Soft Port contains 1 Soft Port.
- Each Soft Port is surrounded by 4.5 inch x 5.5 inch (11.4cm x 14cm) of polyurethane film.
- The Soft Port film extends from the suction opening to ensure an effective seal of the Soft Port to the top of the Transparent Film covering the wound.
- It is important to align the opening of the Soft Port with the opening in the Transparent Film to ensure a good seal and decrease the risk for a false blockage alarm.
- The Soft Port opening is .25 inches (0.6cm) in diameter. It is important that the opening in the wound Transparent Film be .25 inches (0.6cm) in diameter as well.
- When making the opening in the wound Transparent Film, remove any loose edges from the film to prevent aspiration into the Soft Port, possibly causing a false blockage alarm.
- Single Soft Ports are available to assist when Y-Connecting multiple wounds and/or other applications.
- Single Soft Ports are sold separately in the RENASYS Port Kit – individually wrapped and sterile.
- All Soft Port dressings can be left in place up to 72 hours.

## The Soft Port is encased in a white covering

1. Patient dignity – exudate in the Soft Port channel is more discreet with the opaque white covering.
2. The white coloring reflects any color changes occurring within the fluid – most prominently, blood and color changes that may be associated with presence of bacteria. For example:

### Bright red coloration

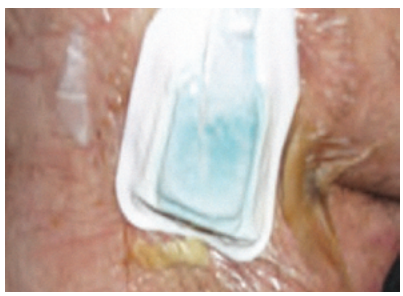
The visual appearance of a bright red color within the RENASYS Soft Port may signal a more critical concern, as this is normally associated with high concentrations of whole blood.

### Important customer reminders:

- If blood is visible in the Soft Port before the blockage alarm activates, clinicians should stop therapy immediately and take the relevant corrective actions.
- The RENASYS Soft Port IFU states haemostasias should always be achieved prior to initiating NPWT.

### Blue/green coloration

- The visual appearance of a blue/green color within the RENASYS Soft Port supports a conclusion that Pseudomonas species has colonized the wound.
- The color is from a pigment created by the Pseudomonas species called pyocyanin.
- A characteristic smell may also be noted when this type of effect is noted.
- You may also see gauze dressings similarly colored in this way.



# Advanced dressing applications

## Y-connector

- RENASYS◊ Y-connector can be used to connect one or two wounds through two RENASYS Soft Ports◊ to a single pump.
- The RENASYS Y-connector can be used with both the RENASYS TOUCH and EDGE Systems.
- Do not use the Y-connector on two wounds if the RENASYS pump display refers to the use of the Y-connector on one wound only.

**Caution:** A RENASYS Y-connector should not be used to treat flaps, grafts or open abdomen wounds in a two-wound configuration. Do not connect an infected and non-infected wound using a Y-connector.

**Note:** RENASYS Y-connector is compatible with RENASYS-G gauze Dressing Kits with Soft Port, RENASYS-F Foam and White Foam Dressing Kits with Soft Port and RENASYS AB abdominal dressing kit with Soft Port.

## The following wound types may be used with RENASYS◊ that is utilizing a RENASYS Y-Connector:

- Flaps and grafts (only in one wound configuration)
- Open abdomen (only in one wound configuration and ONLY with RENASYS TOUCH and RENASYS AB Abdominal Dressing Kit)
- Chronic
- Acute
- Traumatic
- Sub-Acute and dehisced wounds
- Ulcers (such as pressure or diabetic)
- Partial thickness burns

When the RENASYS Y-Connector is used with RENASYS AB Abdominal Kit with Soft Port (only in one wound configuration) and RENASYS TOUCH, it is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera including but not limited to abdominal compartment syndrome. The use of RENASYS Abdominal Kit with Soft Port◊ is intended for use in acute hospital care settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating room.

## Managing multiple wounds

- If both wounds must be monitored, consider a bridging technique using a single Soft Port instead of a Y-connector. Also consider using two devices.
- When treating separate wounds, or utilizing two devices, the clinician should regularly check the wound being treated with the drain or Soft Port to ensure the dressing is compressed.
- Avoid using a RENASYS Y-connector to connect wounds that would be optimally treated using differing pressure settings.
- The same type of dressing kit should be used when treating two wounds using the RENASYS Y-connector.

## Using a Y-connector

1. Prepare the wound site in accordance with the instructions for the relevant RENASYS◊ dressing kit.
2. Prepare the pump for use in accordance with the setup instructions provided in the relevant pump manual. Do not initiate therapy.
3. Connect the RENASYS Y-connector main channel to the canister tubing by pushing the orange quick click connectors together. An audible click indicates the connection is secure.
4. Connect the Soft Ports◊ and/or drains to the RENASYS Y-connector branches. An audible click will indicate that the connection is secure.
5. Activate the RENASYS pump ensuring that it is operating at the prescribed therapy level. The recommended therapeutic pressure range is -80mmHg to -125mmHg when using a Y-connector. The pressure setting must be determined by a healthcare professional based on an individual assessment of the wound.
6. It is recommended to leave the pump connected to the mains power or check the battery status of the pump frequently when using a RENASYS Y-connector.
7. The use of two Soft Ports in conjunction with a RENASYS Y–connector and RENASYS EDGE is recommended when the pump's pressure setting is set below -125mmHg. If a pressure setting above -125mmHg is required, a RENASYS TOUCH should be used. If the RENASYS Y-connector is not appropriate, use two separate pumps to handle the additional demand for delivering negative pressure to both wounds.
8. Confirm that the RENASYS pump has been activated in accordance with relevant pump manual.
9. Check that NPWT is being delivered to the wound site(s). Confirm that the dressing has a raisin–like appearance and is firm to the touch.

### RENASYS Y-connector changes and temporary detachment

10. RENASYS Y-connector should be changed once a week or with each canister change (whichever is sooner). Refer to the specific RENASYS pump manual for instructions on how to change the canister.
11. When bathing or showering the patient must disconnect from the Y-connector leaving it on the pump. Use the Connector caps on the Soft Port and Y-connector to avoid leakage of wound fluid. Ensure the aeration disc located near the orange quick click connector is free of moisture before reactivation of therapy to ensure proper alarm functionality and prevent interruption in therapy.

### RENASYS Y-connector removal/disposal

12. Turn off the RENASYS pump.
13. Disconnect the Y-connector from the Soft Port by applying gentle pressure to the quick click connector and then pulling the connectors apart. Use the caps to cover the quick click connector on the Soft Port and the Y-connector.

### Disconnecting the Quick Click Connectors and using the caps to avoid fluid leak.

14. Remove the canister while still connected to the RENASYS Y-connector from the pump and dispose of both canister and Y-connector.

## Bridging away from the wound

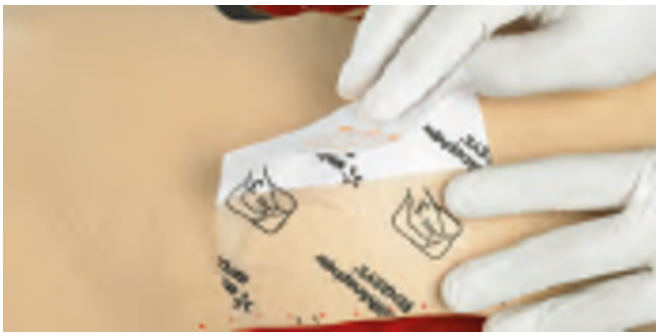
- Under normal circumstances using Soft Port◊, it should not be necessary to bridge away from wounds. If this is the case, please refer to dressing application section.
- If there is still concern that the Soft Port may create pressure at the wound, due to the wound's location and conditions, or if the wound is smaller than the Soft Port opening (1.5cm), utilize the bridge technique. This technique will allow the Soft Port to be redirected to a non-weight bearing area.

# Bridging dressings

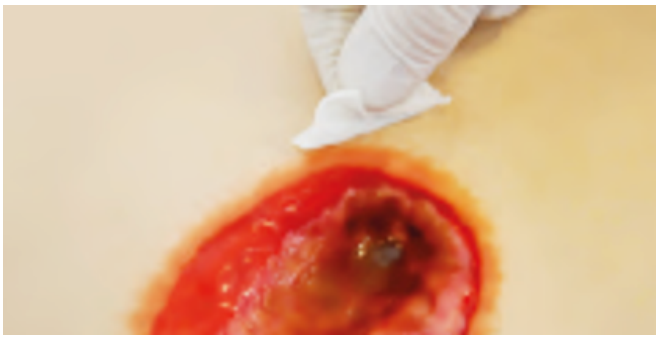
The bridging technique is used to join two wounds that are close in proximity and/or to position the Soft Port in an area away from the wound.

## How to bridge wounds

1. Protect intact skin in area under bridge and between the wounds with transparent film.
   - Consider bridging two wounds together using wound filler for wounds separated by a distance less than 25cm. If the wounds are greater than 25cm consider using a Y-connector.
   - Cut additional foam or gauze and place on top of transparent film to form the bridge.



2. Complete NPWT dressing application technique for the RENASYS◊-F foam or RENASYS-gauze dressings – covering both the wound and bridge with transparent film.



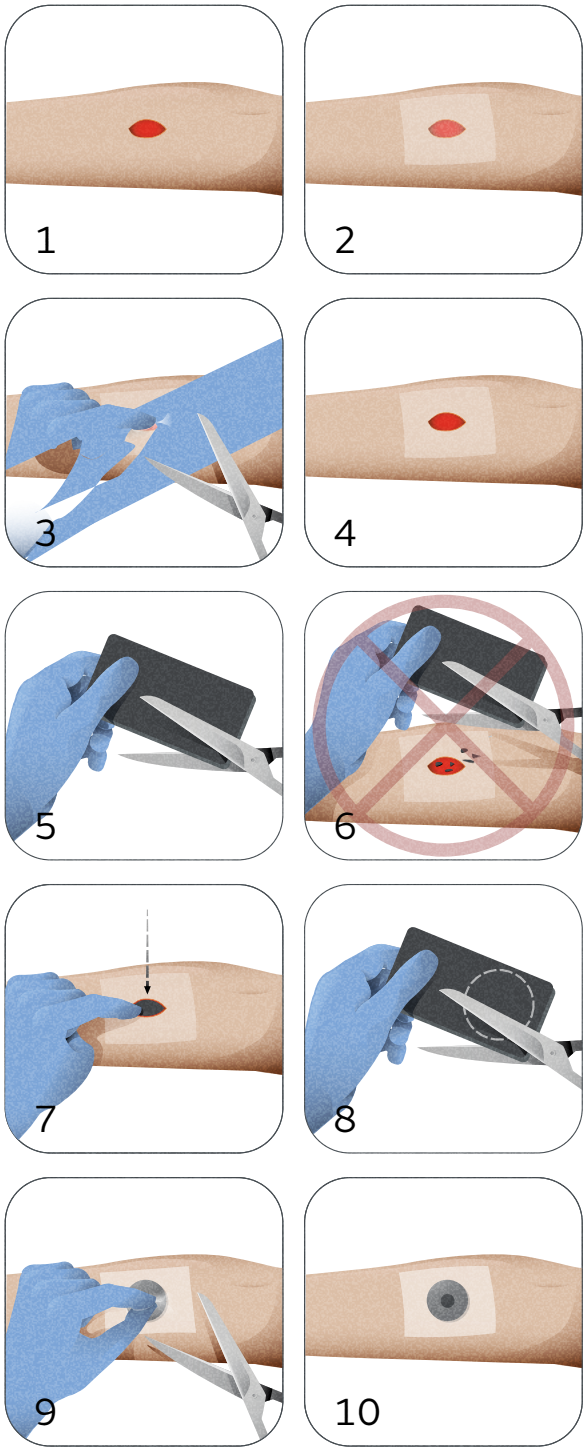
3. Initiate negative pressure.

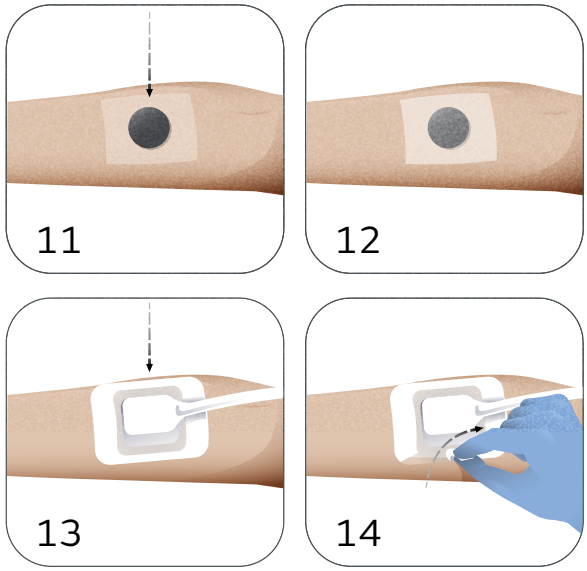
**Note:** When using a bridging technique, choose a location where the bridge is least likely to be weight bearing. This will support the bridge remaining open to optimize transfer of fluid and vacuum.

**Note:** To optimize transfer of fluid and vacuum through the bridge, the foam dressing is recommended. In the instance where gauze is used, particularly for large volume and surface area wounds with moderate to heavy drainage, more frequent inspection of the dressing and dressing changes may be required.

## Dressing small wounds ("mushroom technique")

For wounds that are <4cm, the following dressing application is recommended to protect the periwound tissue and prevent maceration.




- Prepare the peri wound area by following institution protocol, and 'picture frame' or 'window pane' the wound with a hydrocolloid dressing or vapor-permeable adhesive film dressing.
- Cut foam dressing to dimensions that will allow the foam to be placed gently into the wound, but not overlap onto intact skin.
- Gently place foam into wound cavity, ensuring contact with all wound surfaces. Do not force foam dressing into any area of the wound.
- To accommodate the size of the dressing, cut another piece of foam large enough to extend 2-3cm beyond the dressing and lay on the foam in the wound. Assure the foam does not extend onto intact skin, that it is positioned on the product used to 'picture frame' the wound and protects the intact skin.
- Trim and place the drape to cover the foam dressing and an additional 3-5cm border.
- Pinch drape and cut a 2.5cm hole through the drape (not a slit). The hole should be large enough to allow for removal of fluid and/or exudate. It is not necessary to cut into the foam.

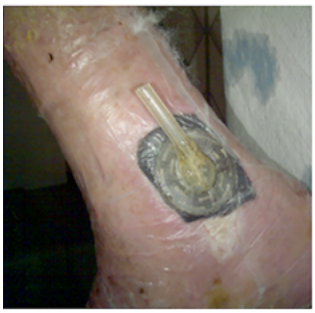
**Note:** Do not cut the foam over the wound, as fragments may fall into the wound. Away from the wound site, rub or trim foam, removing any fragments to ensure loose particles will not fall into or be left in the wound upon dressing removal.
**Note:** Always count the total number of pieces of foam used in the wound. Document the foam quantity and dressing change date on the Foam Quantity Label if available, and in the patient's chart.

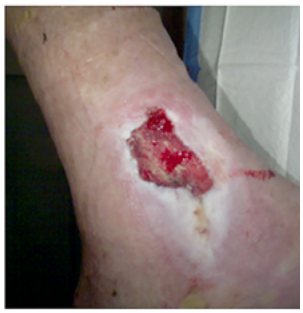
## Undermining and/or tunneling

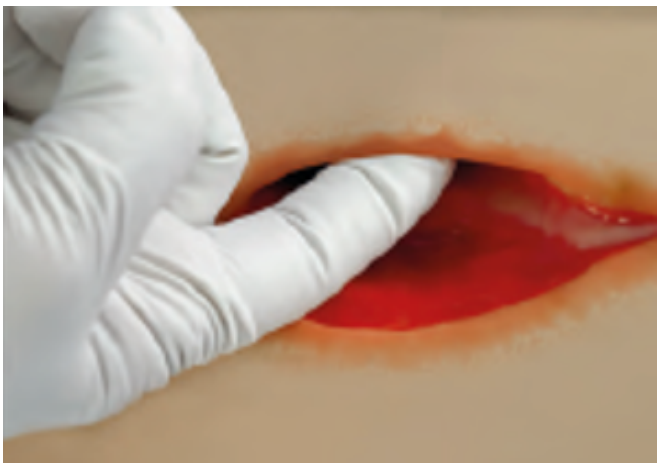
Undermining is a lateral tissue defect or pocket under the edges of the wound. The surface opening is smaller than the base of the wound.

### How to manage undermined wounds

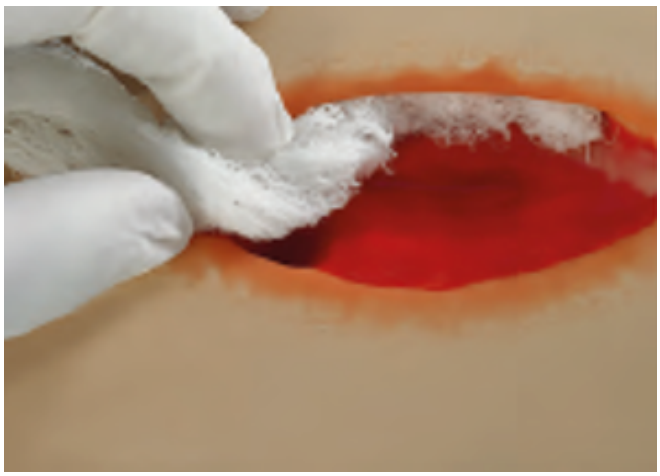
1. Utilizing saline moistened gauze, loosely fill the undermined areas and any dead space of the wound.





2. Once the undermined areas have been filled with moistened gauze, gauze or foam may be used to fill the remainder of the wound making sure that all areas of the wound are in contact with wound filler.

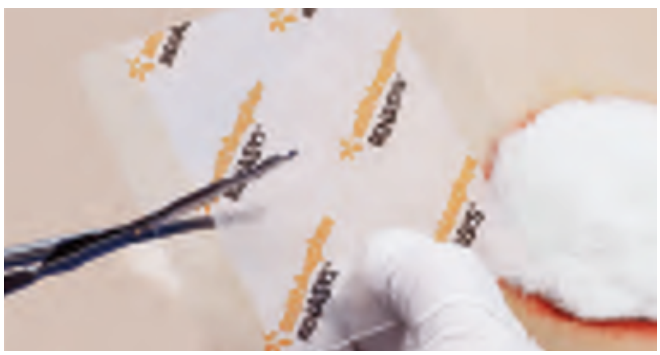


3. Cover with transparent film as indicated.
4. Continue with RENASYS◊ dressing application technique, seal the wound.

### How to guides for creating seals

#### How to create a seal around drain tubing

1. Cut the gel patch into strips in a direction with backing removal ends accessible.

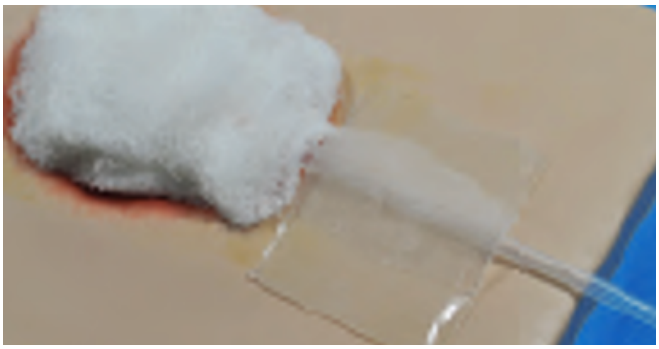


2. Remove the backing on one side only and apply to skin with gentle pressure.

3. Remove the remaining backing and apply tubing.

4. Apply another strip using the same technique over the top of the tubing.

5. Apply another strip using the same technique over the top of the tubing.

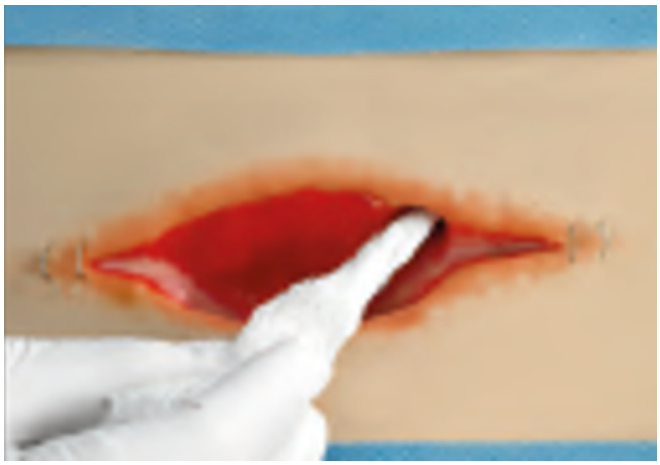


## Tunneling or sinus tracts definition

- A tunnel or sinus tract is a narrow opening in the wound bed that extends into adjacent tissue.
- White foam is recommended for use in tunnels.
- Always trim white foam dressing so it is broader at one end and tapers towards the other. This technique ensures that the entrance of the tunnel or sinus tract remains open until the farthest part of the tunnel has healed and closed.

## How to address tunnels or sinus tracts

1. Fill tunnels or sinus tract with moistened gauze or sterile packing strips, pulling out/back 0.5 to 1cm to allow for healing distal to proximal.



2. Make sure the tunnel filler material is visible and accessible in the wound bed to assure complete removal upon dressing change.
3. Filler material in tunnels may contract when compressed, it is important to leave a tail to facilitate removal.
4. Continue with RENASYS dressing application technique utilizing gauze or foam assuring that all areas of the wound are in contact with the wound filler.

**Note:** Do not place foam into blind or unexplored tunnels.

**Note:** If multiple pieces of foam are needed, count and record the number of foam pieces used.

# Skin grafts

## Treatment goal

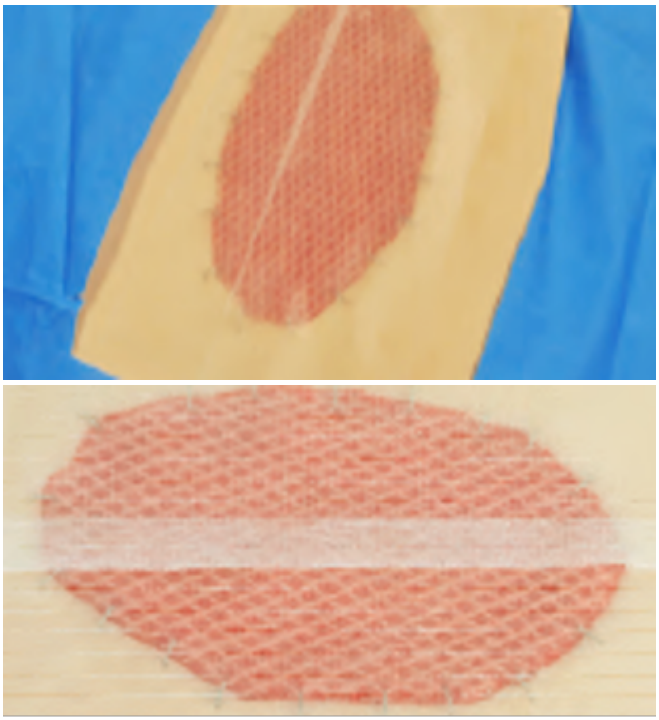
- Bolster the graft in place to prevent shearing and minimize movement of the graft.
- Eliminate accumulation of wound fluid beneath the graft that could lead to the graft lifting and impact upon graft take.

## Suggested pressure setting and dressing change frequency

- Pressure setting recommendation is -40 to -125mmHg in continuous mode.
- Ultimately, the pressure setting is a decision to be determined by the physician/clinician. Generally, lower pressure settings are utilized (-60 to -80mmHg) for skin grafts.
- Foam dressings should be changed per protocol after the initial application of therapy. If no leak is present and the patient is comfortable, dressing changes should occur no less than 3 times per week.
- Gauze dressings should be changed per protocol after the initial application of therapy. If no leak is present and the patient is comfortable, dressing changes should occur 2-3 times per week.
- Exudate level should decrease after the first 24-48 hours.
- Duration of therapy is also a physician/clinician decision (generally 3-10 days).
- Negative pressure wound therapy (NPWT) should remain on continuously to ensure the graft always remains bolstered.
- When utilizing a dressing kit, it is important to apply a wound contact layer between the graft and the filler to avoid adherence to the foam or gauze.[27]

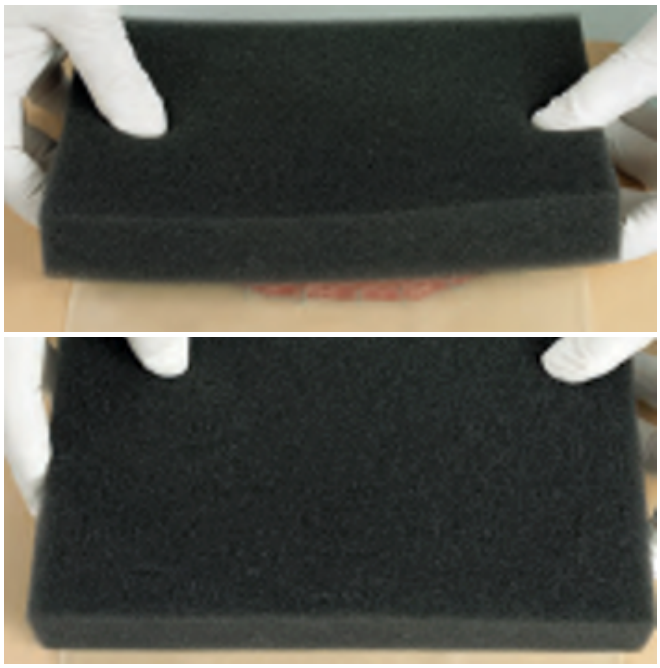
## How to dress a skin graft with RENASYS◊ Soft Port◊

1. Cover the entire graft with a non-adherent layer and extend the contact layer at least 1 inch (2.54cm) past the suture/staple line.



2. Cut foam or gauze to the size and shape of the contact layer so it does not extend past the wound contact or come into contact with healthy skin. This will help avoid damage to surrounding tissue.

3. Place cut foam or gauze on top of the contact layer.



Continue with RENASYS dressing application technique to seal the wound.

# Fistula management: Isolation technique

1. Clean the wound according to facility protocol and isolate the fistula by wrapping a non-adherent gauze or barrier around the base of the fistula to protect from drainage.
2. Utilize gauze or other absorptive material at the opening of the fistula to manage drainage while dressing the wound. May also use wall suction with catheter to manage effluent during dressing application.
3. Cover the base of the wound with non-adherent layer if necessary.
4. Cut and fit the foam or gauze dressing into the wound. **Important:** Do not place foam or gauze wound fillers over the opening of the fistula.
5. Apply film dressing over the wound and attach Soft Port dressing. Initiate negative pressure wound therapy (NPWT) to ensure that a seal is achieved.
6. Once seal has been achieved, turn therapy off, and gently cut a hole in the dressing directly over the covered mouth of the fistula to expose mouth.
7. Remove gauze covering from mouth of fistula and expose the fistula to attach an ostomy appliance or fluid collection device of choice.
8. Initiate NPWT and apply the collection device to isolated fistula ensuring a good seal.
9. Use continuous therapy and monitor canister and dressing frequently.

**Note:** It is important that the mouth of the fistula be visualized to utilize the isolation technique.

## Types of fistula:

- Fistulas can be internal or external:
  - **Internal** – communication is between a body cavity or hollow organ to another body cavity or hollow organ.
  - **External** – communication between a hollow organ and the skin.

## Fistula terminology – Described by the anatomic location or the site of origin and the site of termination.

Example of fistula terminology

| Name | From | To | Type |
|---|---|---|---|
| Enterocutaneous | Intestine | Skin | External |
| Recto-vaginal | Rectum | Vagina | Internal |

## Fistulas may also be described by amount of output:

- High output – 500ml or more/24 hours
- Moderate output – 200-500ml/24 hours
- Low output – less than 200ml/24 hours

The wound surrounding the fistula opening should respond as any other wound on NPWT by displaying decreased size, decreased drainage, and increase in granulation tissue. The fistula opening will likely require surgical intervention or pouching depending on the maturation of the fistula.

**Note:** Patient's parenteral intake should be considered. Patient's fluid levels should be closely monitored, particularly with infants, children and geriatrics.

## RENASYS◊ adhesive gel patch

- The RENASYS adhesive gel patch is intended for fixation of drainage tubing and is a useful accessory to help improve seals, especially in challenging anatomical areas or with challenging wound and skin conditions.
- The gel patch is made of a double-sided adhesive hydrogel sheet.
- This adhesive gel patch can be used as an alternative to ostomy paste. The wear time is up to 72 hours.

### Application tips

- The RENASYS adhesive gel patch is intended to be used on intact skin. It is primarily used to improve seals and avoid leaks.
- Used under the RENASYS transparent film, the gel patch can be cut and placed around the periwound area prior to sealing with the RENASYS transparent film.
- It may be easier to cut or shape the RENASYS gel patch prior to removing the adhesive backing.
- When using gloves, remove one side of the adhesive backing and apply to the skin. Remove the remaining panel once placed.
- The gel patch has absorbent properties, which means it can absorb reasonable amounts of fluid. Depending on the wound output and conditions, it is possible to overwhelm the dressing if enough fluid comes in contact.
- More frequent dressing changes may be needed as directed in the Instructions for Use for RENASYS-G gauze or RENASYS-F foam dressing kits.

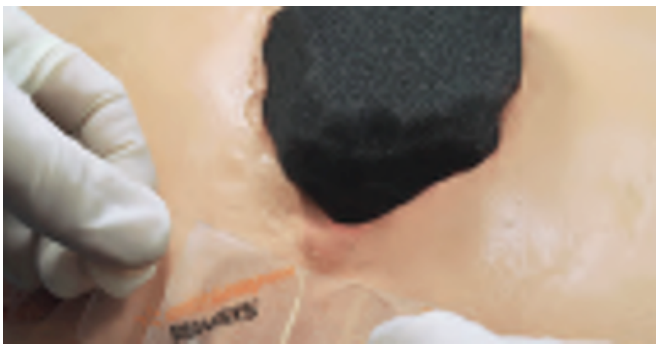
### Product application areas

- Fixation around drainage tubing
- Protection around wound margins
- Challenging anatomical areas such as skin folds
- Areas with moist skin
- External fixation pins

## How to create a seal in challenging anatomical areas

1. Cut the gel patch into strips in a direction with backing removal ends accessible.

2. Remove the backing on one side only and apply to skin with gentle pressure. Ensure the fold is addressed first.

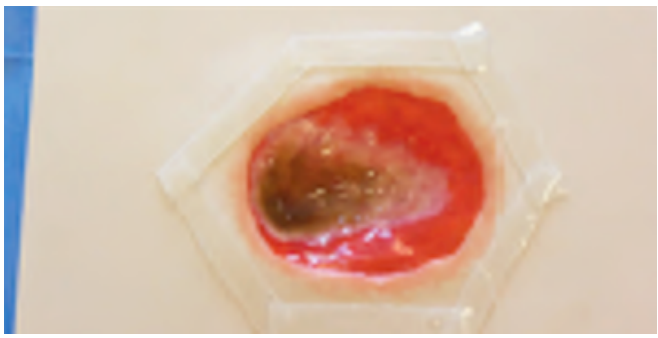


3. Remove the backing. Apply transparent film over the foam or gauze interface and the gel patch to create a seal and finish the dressing.

## How to create a seal around wound margin

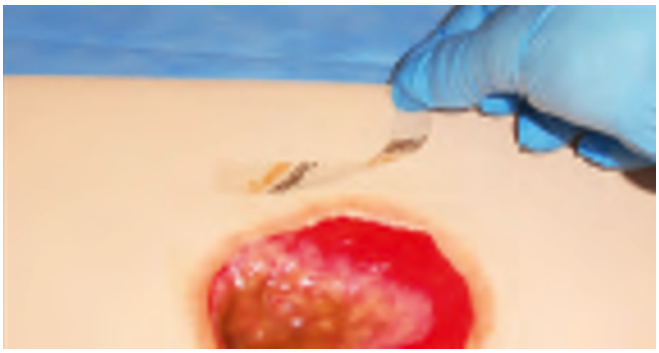
1. Cut gel patch into several strips. Remove the backing on one side only and apply to skin with gentle pressure. Remove the backing.


2. Continue to apply gel strips around wound margins ensuring that the strips overlap to create a good seal. Continue with normal dressing application.

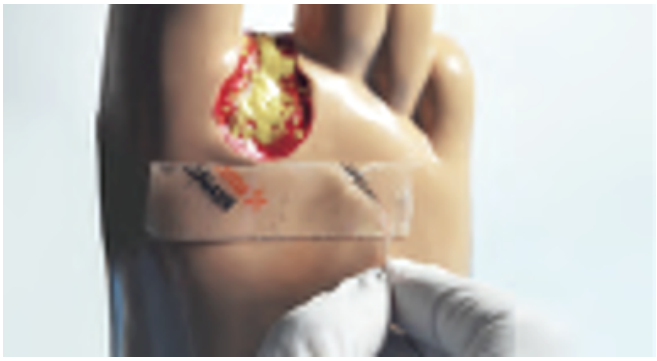


## How to create a seal in challenging areas of the foot

1. Cut the gel patch into strips in a direction with backing removal ends accessible.



2. Remove the backing on one side only and apply to skin with gentle pressure. Ensure the fold is addressed first.

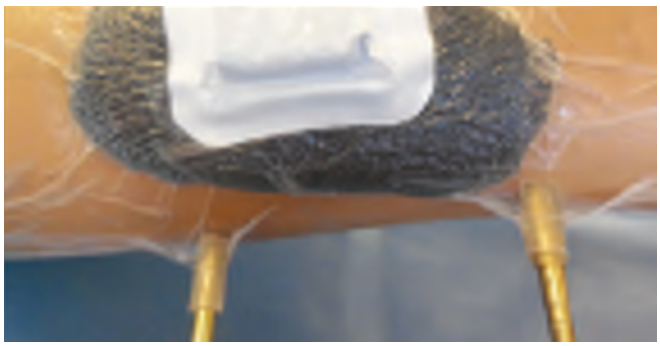


3. Remove the backing. Apply transparent film over the foam or gauze interface and the gel patch to create a seal and finish the dressing.

## How to create a seal around external fixation pins

1. Cut gel patch into strips and to a length that will cover the pin circumference.
2. Remove the backing on one side only.
3. Apply the lead end of the gel strip to the base of the pin.
4. Gently apply pressure to the backing to ensure initial adhesion to the pin.
5. Wrap the gel strip around the pin while simultaneously removing the backing.

6. Apply transparent film over the foam or gauze interface and the gel patch.
7. Pinch the film at the gel patch/pin interface to create a seal and finish the dressing.



## Introduction

- In the past decade there has been increasing evidence to suggest that using temporary abdominal closure techniques can help to reduce mortality in patients with intra-abdominal hypertension and help prevent development of Abdominal Compartment Syndrome.[28]
- Negative pressure dressings have been used for several years to help facilitate temporary abdominal closure and have been proven to be a reliable treatment due to excellent clinical benefits in appropriate circumstances.
- The primary aim of temporary abdominal closure is to reduce pressure within the abdominal cavity.
- Reducing the intra-abdominal pressure, can prevent or reduce the risk of the patient developing Abdominal Compartment Syndrome.[28] Reducing the pressure in the abdominal cavity also reduces the likelihood of respiratory, renal and cardiac complications.[28]

## Indications for use

- The RENASYS◊ AB abdominal dressing kit with Soft Port is intended for use in conjunction with RENASYS TOUCH devices and canisters as a complete Negative Pressure Wound Therapy (NPWT) System for managing open abdominal wounds with NPWT.
- RENASYS AB is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary.
- It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to Abdominal Compartment Syndrome.
- The use of RENASYS AB is intended for use in acute hospital care settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating room.

## Contraindications

The use of RENASYS AB is contraindicated for:

- Non-enteric, unexplored fistula.
- Untreated osteomyelitis.
- Malignancy in the wound (with exception of palliative care to enhance quality of life).
- When vital organs and structures are not covered with the Organ Protection Layer (OPL).
- Presence of necrotic tissue with eschar.
- Use in patients with on-going or high potential for hemorrhage and/or enteric leak.

Foam should never be placed in contact with exposed bowel, arteries, veins, organs, or nerves. Always utilize the OPL when using the RENASYS AB with the RENASYS NPWT System.

## Protecting vessels and organs

- Caution should be taken to ensure that all organs and/or vessels are completely covered prior to initiating NPWT.
- Do not place dressings directly in contact with exposed bloody vessels, anastomotic sites, organs or nerves.
- It is the responsibility of the treating clinician to determine the appropriate natural tissue and/or non-adherent wound contact layer to be utilized to protect and prevent organs or vessels from having direct contact with NPWT.
- When using a non-adherent wound contact layer, the treating clinician should consider utilizing multiple layers and securing to prevent movement during NPWT.

**WARNING:** The use of NPWT is contraindicated and should never be placed in direct contact with exposed vessels and organs.

## Abdominal Dressing Kit

- Non-enteric, unexplored fistula.
- Untreated osteomyelitis.
- Malignancy in the wound (with exception of palliative care to enhance quality of life).
- When vital organs and structures are not covered with the Organ Protection Layer (OPL).
- Presence of necrotic tissue with eschar.
- Use in patients with on-going or high potential for hemorrhage and/or enteric leak.

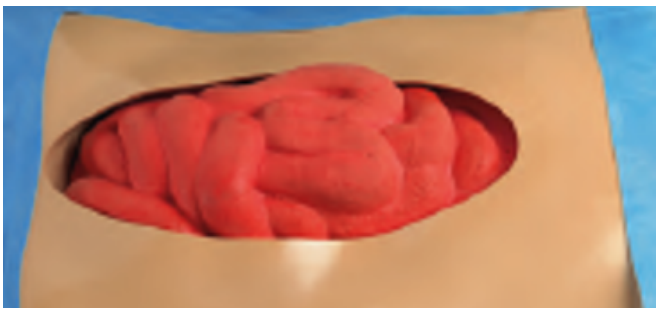
Foam should never be placed in contact with exposed bowel, arteries, veins, organs, or nerves. Always utilize the OPL when using the RENASYS AB with the RENASYS NPWT System.

# Abdominal Dressing Kit: Dressing application technique

## Step 1

### Preparing an open abdominal wound

1. Eliminate any sharp edges or bone fragments from wound area (refer to PRECAUTION Section).
2. Ensure any areas of necrosis are appropriately debrided.
3. Irrigate abdominal wound as needed.
4. Clean and dry the periwound area.



**WARNING:** Review all RENASYS NPWT System safety information prior to beginning wound preparation.

**Note:** Ensure that sufficient hemostasis has been achieved prior to applying the RENASYS AB dressing (refer to WARNINGS SECTION).

## Step 2

### Applying an Organ Protection Layer (OPL)

1. Remove kit contents from pouch and prepare the OPL on a sterile field. If cutting the OPL to a different size, ensure that each piece removed has been disposed of properly, away from the open wound.

2. Gently position the OPL dressing evenly into the abdominal cavity, distributing the sides into both of the lateral paracolic gutters. Any excess material on the sides of the OPL may be folded back onto itself

3. Ensure complete coverage of all exposed bowel in the abdominal cavity with the OPL, prior to filling the wound defect with foam.

**WARNING:** Always protect vital structures such as bowel and abdominal organs with the Organ Protection Layer (OPL) during therapy. Foam should never be placed in contact with exposed bowel, arteries, veins, organs, or nerves (refer to CONTRAINDICATIONS SECTION).

**Note:** Either side of the OPL may be applied to exposed organs. The OPL may be cut or folded to accommodate the specific needs of the patient. Moistening the gloves may aid in application of the OPL.

## Step 3
### Perforated foam application

1. Size the provided foam to the desired proportions along prescored perforations. Cutting the wound filler may be performed if desired. Do not cut the foam wound filler directly over the wound bed to avoid foam fragments from falling into the wound. Rub the edges of any cut foam, away from wound, to remove any loose fragments which may result. The foam should be placed directly over the Organ Protection Layer (OPL) while maintaining contact with the margins of the wound.

2. Gently place perforated foam in the wound cavity over the OPL. Ensure that foam is sized to fit loosely into the wound defect and there is sufficient material up to the top surface of the abdominal wound (do not under fill the wound).

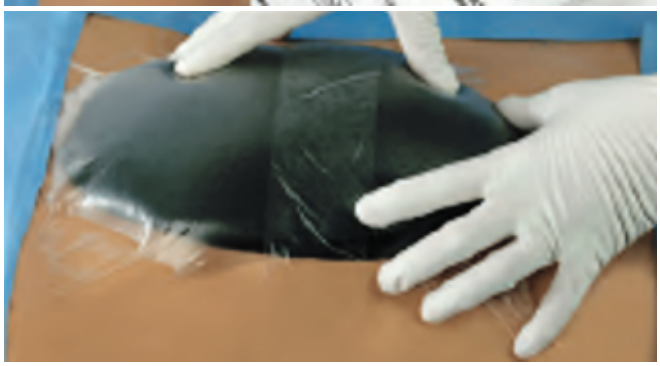
**Note:** Do not allow foam to contact intact skin without use of appropriate barrier, such as transparent film or a hydrocolloid. It may be necessary to stack pieces of foam in deep wounds depending on the wound profile. If multiple pieces of foam are needed, count and record the number of foam pieces used.

**WARNING:** Do not tightly pack or force foam into any areas of the wound.

## Step 4
### Transparent film application

1. While holding the transparent film, expose one side of the adhesive backing by removing a single panel and apply it to the foam.

2. Cover foam with transparent film, removing remaining adhesive panels to seal, as well as the remaining carrier panel. Film should extend at least 5cm/1.97in beyond wound margin and be securely anchored to periwound area to maintain a good seal.

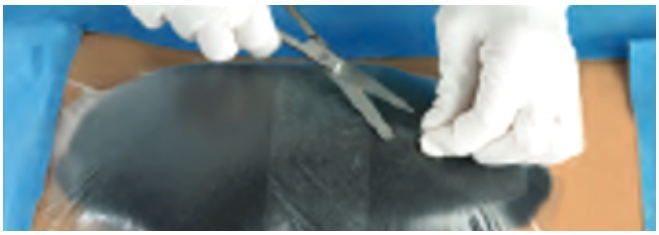


**Note:** Overlap the edges of the transparent film by a minimum of 7.5cm/2.95in when using multiple pieces of transparent film. Avoid stretching or pulling the transparent film to minimize tension or trauma to the peri wound skin.

## Step 5

## Apply a RENASYS◊ Soft Port◊

1. Cut a circular opening (no less than 1 inch in diameter) in the center of the film, over the wound filler. Remove any loose transparent film and dispose of away from the wound.



2. Remove the adhesive panel from the RENASYS Soft Port dressing and align the port opening directly over the hole in the transparent film.

3. Align the Soft Port opening directly over the hole in the transparent film. Use gentle pressure to anchor the Soft Port to the transparent film.

4. Smooth the dressing down while removing the RENASYS Soft Port top stabilization frame.

5. Secure the RENASYS Soft Port to the patient according to your institutional protocol. Ensure the aeration disc, located near the quick click connector, is not covered or otherwise occluded by the method used to secure the Soft Port.

6. Connect the RENASYS Soft Port to the canister tubing by pushing the quick click connectors together.

7. Turn on the RENASYS◊ pump, adjust the pump to the prescribed therapy level and then activate the RENASYS pump.


8. Finished dressing should be firm to the touch and leak free.

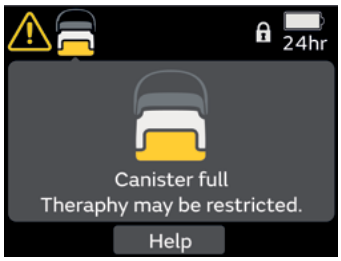
# Troubleshooting: RENASYS◊ EDGE pump light indicators

## Maintaining pump functionality

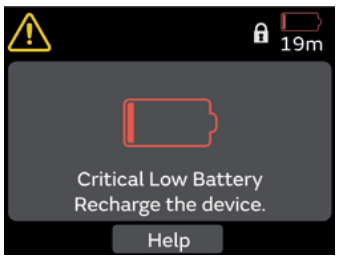
The RENASYS System has visual indicators to let the user know when there is an issue. The pump should be carried so that it is accessible, and the patient/healthcare professional can check the status routinely in case there is a fault or in case of damage.

### Alarms


Blockage

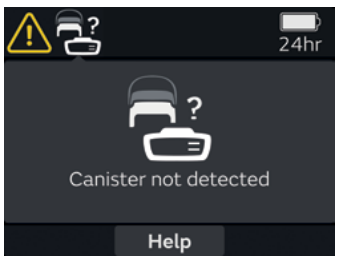



Canister full

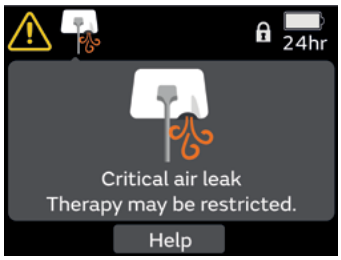



Critical low battery

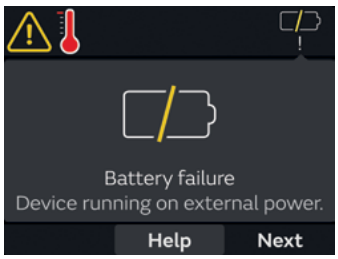

Pump too hot



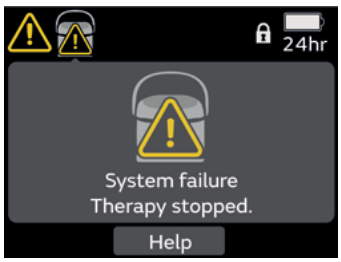

Canister missing




Critical air leak

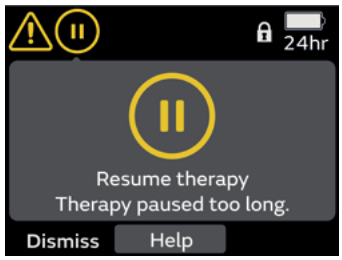



Battery failure

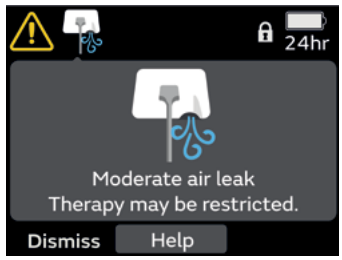



High vacuum/System failure

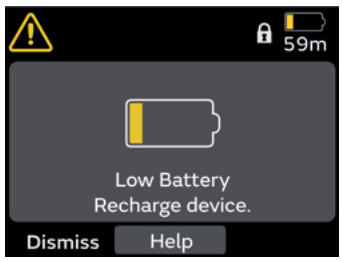
### Alerts




Therapy paused too long




Moderate air leak




Low battery

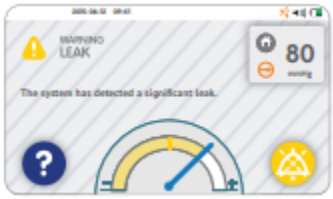

Pump too hot for charging

# Troubleshooting: RENASYS◊ TOUCH pump light indicators

## Maintaining pump functionality

The RENASYS System has visual indicators to let the user know when there is an issue. The pump should be carried so that it is accessible, and the patient/healthcare professional can check the status routinely in case there is a fault or in case of damage.

### Alarms

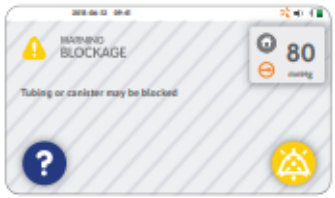


Leak

Low vacuum

High vacuum

Over vacuum



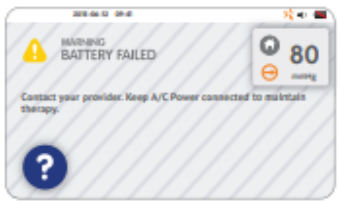
Blockage

Canister full

### Alerts

Low battery

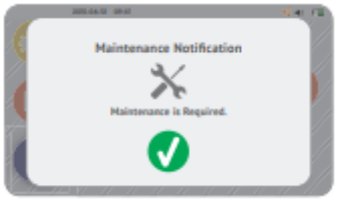
Critical battery



Battery failed

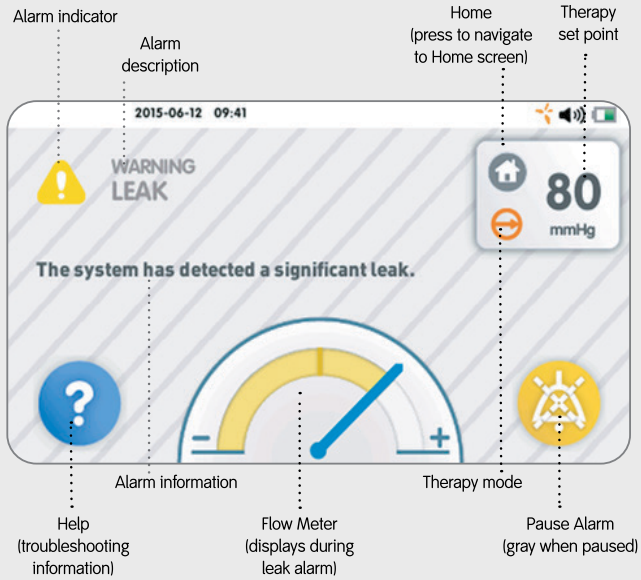
Device failed

Inactive



Annual maintenamce

### RENASYS TOUCH pump light indicators



## Frequently asked questions

### *What is the range of pressure that the device achieves?*

- RENASYS◊ TOUCH: 0mmHg to -200mmHg
- RENASYS EDGE: -25mmHg to -200mmHg

### *Is the pressure pre-set?*

- The pressure on RENASYS TOUCH is pre-set to -80mmHg. It may then be adjusted to the desired level.
- The pressure on the RENASYS EDGE device is pre-set to -125mmHg and then can be adjusted to the desired level.

### *Can the pressure setting be changed?*

- The pressure setting on the RENASYS devices can be changed.
- The pressure setting should be determined by the prescribing clinician based on an individual assessment of the patient and wound.

### *Is there a variable intermittent mode and when should I use it?*

- The RENASYS TOUCH and EDGE devices can deliver intermittent and variable intermittent NPWT using tailored time settings defined by the clinician.

**Note:**

- Experimental studies have shown improvements in the rate of granulation tissue formation, wound contraction, and blood flow with intermittent and variable NPWT compared with continuous NPWT.[22,30-32]
- Some reports suggest that intermittent NPWT may be painful in susceptible patients.[33]
- Patients being treated with variable NPWT have been shown to report less pain compared with intermittent pressure.[30]
- The choice to use continuous or intermittent therapy should be based on clinical judgment and the therapy objective of the wound being treated.

### *Should I change the canister only when the canister full alarm is initiated?*

- Canisters should be changed at least once a week, whenever there is a change of patient or in the event the canister contents reach maximum volume indication.
- Do not wait for canister over-capacity alarm activation to change canister.
- A thorough assessment of the device and wound should be performed regularly.
- If two 300ml canister changes occur without the canister full alarm, consider changing to PICO◊ sNPWT System.

### *Is fluid prevented from coming back through the tubing towards the patient?*

- The RENASYS canisters contain a gelling agent that becomes a gel when in contact with fluid which prevents fluid going back through the tubing toward the patient.

### *How long does the battery last?*

- RENASYS TOUCH: up to 16 hours
- RENASYS EDGE: up to 24 hours

### *How much does the machine weigh? (How portable is it?)*

- RENASYS TOUCH is 2.13lbs. (0.967kg) or 2.4lbs (1.1kg) with the 300ml canister fitted.
- RENASYS EDGE is 2.4lbs. (1.13 kg) with empty 300ml canister fitted.

### *What is the interface with the wound?*

For the RENASYS◊ Systems, the wound fillers are black foam, white foam, or gauze.

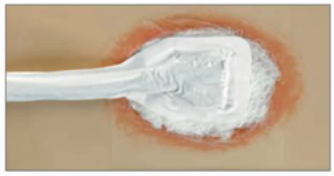
### *How do you handle exposed tendon or bone?*

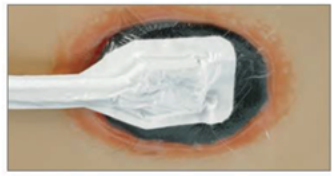
Exposed tendons and bone should be covered with natural tissue or a non-adherent dressing layer prior to applying the NPWT dressing.

## *How do I know if the RENASYS therapy device is working?*

While the RENASYS TOUCH and EDGE therapy devices are turned on a green light will illuminate. The illuminated light located at the top of the device tells you the device is on, and vacuum is working. For RENASYS EDGE, If the device is set to CONTINUOUS mode the selected pressure is displayed on the screen. If the device is set to INTERMITTENT mode, the gauge will show 0 pressure during “off time” and the set pressure while vacuum is occurring.

## *Does the dressing have a raisin-like appearance and firm to the touch?*





## *What can be used to help aid in getting a seal?*

A SECURA No-Sting Barrier Film wipe can be used to help identify where an air leak might be so that additional transparent film can be used to create a seal. RENASYS Gel Patch can also be used to seal leak areas.

## Evidence pyramid and topics

In total, **87** clinical publications that discuss use of RENASYS◊ tNPWT were identified. The highest levels of evidence available are summarized for each topic; therefore, not all studies are included due to volume of publications.

### Levels of evidence


**9**

Randomised controlled trials, systematic reviews and meta-analyses


**5**

Prospective, observational comparative studies


**8**

Retrospective, observational comparative studies


**31**

Case series (prospective and retrospective)


**34**

Case reports letters to the editor, expert opinions

**To access our RENASYS System clinical evidence please scan the QR code below**

# The PICO◊ Single-Use Negative Pressure Wound Therapy System

# Introducing the PICO◊ System

## Overview

The PICO Single-Use Negative Pressure Wound Therapy System (sNPWT), consisting of a pump and sterile dressing(s), delivers continuous -80mmHg negative pressure to aid healing, managing exudate through absorption and moisture evaporation.

## PICO System features

### Reliable performance:

- Employs AIRLOCK◊ Technology for consistent delivery of -80mmHg negative pressure across the entire dressing.
- Effective even on uneven body contours.

### Patient comfort:

- Portable, quiet, and canister-free design.
- Gentle silicone adhesive dressings minimize discomfort upon dressing removal.[30,31,34]
- Portability allows patients to be active during therapy.
- Waterproof dressing allows patients the ability to shower.
- Utility across various clinical settings, including hospitals, outpatient clinics and at home.

### Ease of monitoring:

- Features a 'Start Date' field on back of pump for tracking therapy commencement.
- Includes a 'dressing full' indicator to prompt timely dressing changes.

**Scan for additional resources**

## Indications

PICO◊ Single Use Negative Pressure Wound Therapy Systems are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. PICO Systems are suitable for use both in a hospital and homecare setting.

### 1. Surgical incisions

PICO System is appropriate for closed surgical incisions, including (but not limited to):*

- Orthopedic surgery
- Obstetric and gynecological surgery
- Plastics
- General
- Cardiovascular

When used on closed surgical incisions, the PICO System is intended to aid in reducing the incidence of:

- Superficial and deep incisional surgical site infections for high-risk patients in Class I and II wounds
- Post-operative Seroma
- Dehiscence

### 2. Open wound indications

Use The PICO System in the treatment of hard-to-heal chronic, traumatic and acute wounds, such as:*

- Ulcers (such as diabetic and pressure)
- Flaps and grafts
- Venous leg ulcers (in combination with graduated compression therapy)
- Subacute and dehisced wounds
- Partial thickness burns

* Please reference IFU

## Contraindications

### The PICO◊ System is contradicted for patients with:

- Malignancy in the wound or margins of the wound (except in palliative care to enhance quality of life)
- Previously confirmed and untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Necrotic tissue with eschar present
- Exposed arteries, veins, nerves, or organs
- Exposed anastomotic sites

### The PICO System should not be used for the purpose of:

- Emergency airway aspiration
- Pleural, mediastinal or chest tube drainage
- Surgical suction

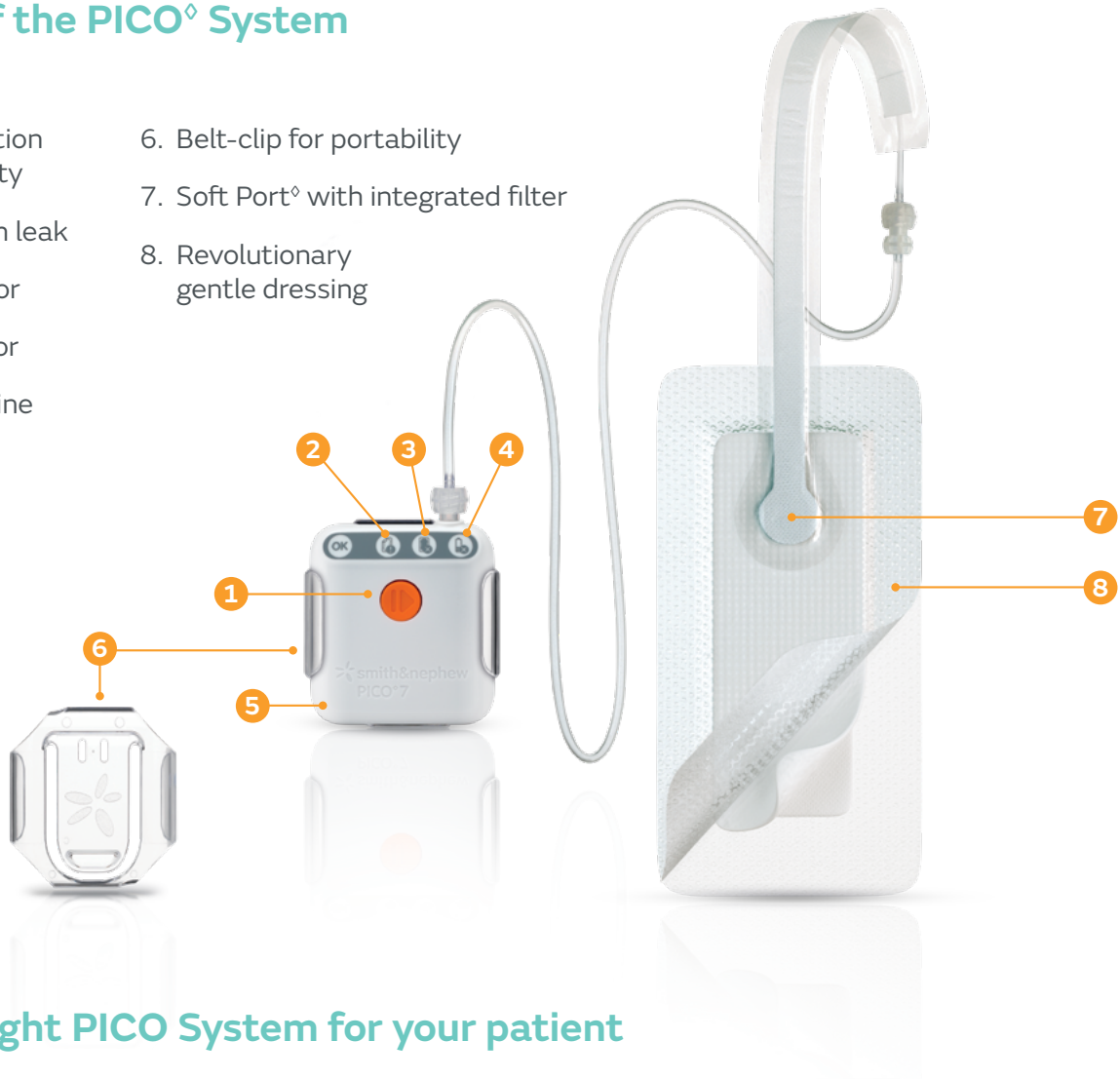
## Adverse Reactions

Excessive bleeding is a serious risk associated with the application of suction to wounds which may result in death or serious injury. Careful patient selection, in view of the above stated contraindications, warnings and precautions is essential. Carefully monitor the wound and dressing for any evidence of a change in the blood loss status of the patient. Notify the healthcare professional of any sudden or abrupt changes in the volume or the color of exudate.

**Important safety information and precautions**

## Components of the PICO◊ System

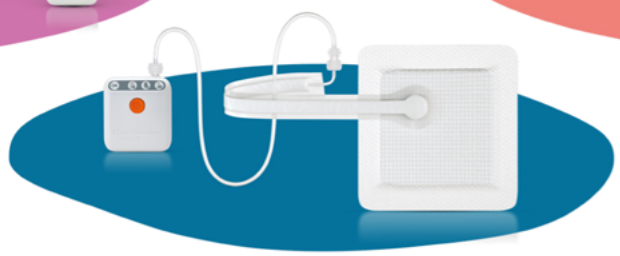
1. Single button operation for ultimate simplicity
2. Indicator for vacuum leak
3. Dressing full indicator
4. Low battery indicator
5. Operates on 2 Alkaline AA batteries
6. Belt-clip for portability
7. Soft Port◊ with integrated filter
8. Revolutionary gentle dressing



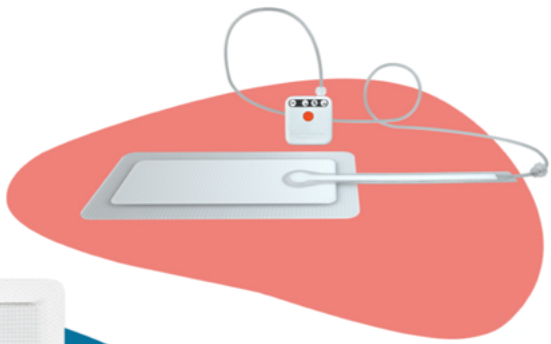

## Choosing the right PICO System for your patient

### PICO Portfolio

**PICO 7Y System**
Designed to treat two wounds on the same patient from one portable device



**PICO 7 System**
A portable system that can be used on open wounds or closed surgical incisions, with a therapy time of 7 days.



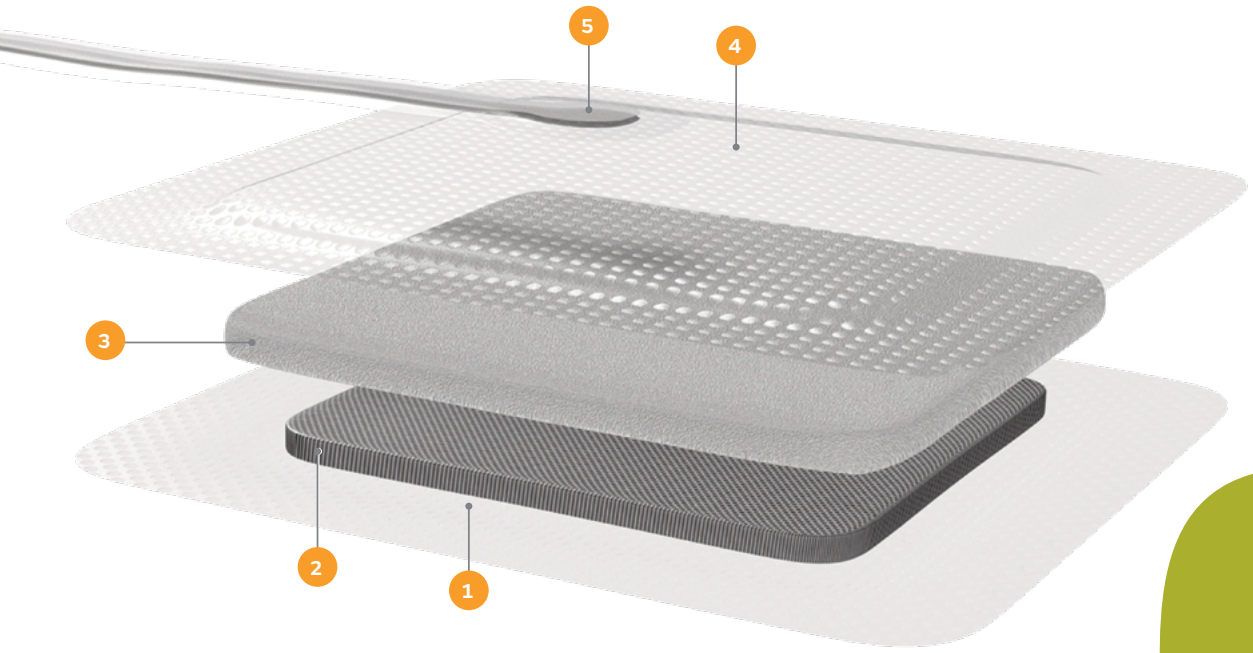
**PICO 14 System**
Delivers the same proven benefits of our PICO 7 sNPWT System with twice the therapy time

# PICO◊ System AIRLOCK◊ technology

The PICO System features an exclusive mode of action that enables delivery of negative pressure wound therapy across the entire dressing to the wound or incision and periwound, while simultaneously removing exudate.[33,40]

## Only **PICO** sNPWT has a proprietary **AIRLOCK*** Technology layer

1. **Silicone adhesive layer** minimizes pain on removal[30]
2. **Pioneering AIRLOCK Technology** transmits pressure evenly across the whole wound bed and surrounding zone of injury†[42]
3. **Super absorbent core** locking exudate away from wound†[42]
4. **Top film layer** has a high moisture vapor transmission rate and protects the wounds from external contamination†[44,45]
5. **PICO** Soft Port with integrated filter






*AIRLOCK is unique and proprietary to Smith+Nephew. † *As demonstrated ex-vivo.*

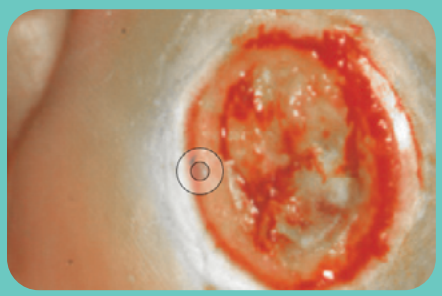
# Support

## Wound selection guidance: open wounds

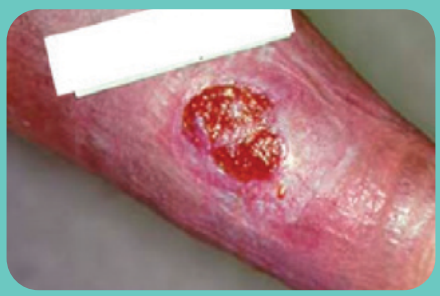
### Is the PICO◊ Negative Pressure Wound Therapy System the appropriate option?

In wounds which responded, PICO Negative Pressure Wound Therapy (NPWT) system has been shown to advance chronic wounds towards healing on average 10 weeks earlier than predicted with standard wound care dressings.*[46]

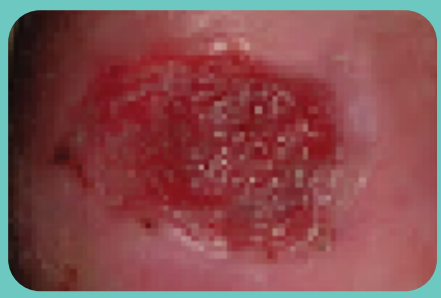
## Some examples of appropriate wounds



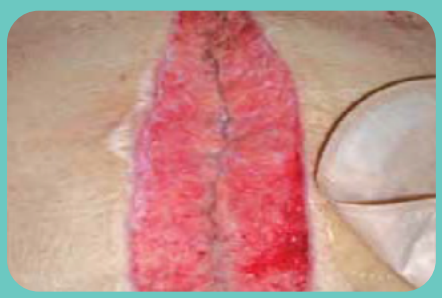
**Diabetic foot ulcer****



**Venous leg ulcer****

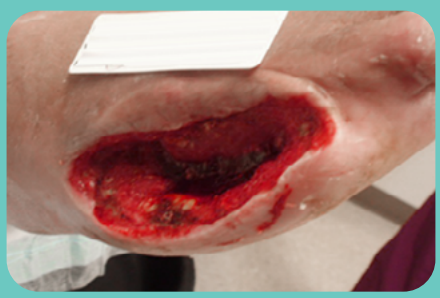


**Pressure ulcer****



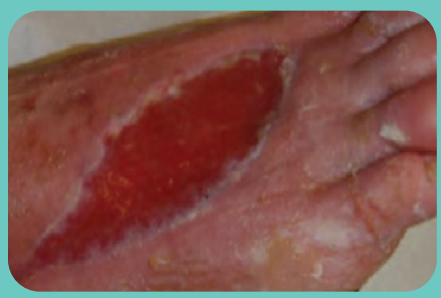
**Surgical dehiscence****

- Filler recommended



**Amputation site****

- Filler recommended
- Conjunctive therapy with offloading



**Traumatic wound****

*Based on 5 out of 9 wounds responding; wound mean duration prior to study 44 weeks, study size n=9.
** Low to moderate exudate

# Is this wound appropriate for PICO◊ sNPWT?

## Step 1 Exudate levels

**Does the wound have low to moderate levels of exudate?**


Yes Continue to Step 2 No Not appropriate

## Step 2 Wound size

**Does the wound fit under 1 of the 8 PICO Dressings?**

Yes Continue to Step 3 No Not appropriate

**Recommendation:** Choosing a dressing size that is slightly larger than the wound allows the benefits of negative pressure to extend to the periwound area.

## Step 3 Wound depth

**Note:** NPWT requires direct contact with the wound bed. Prior to application, assess the wound to determine depth and if a filler would be required.

**Does the PICO System conform to the wound bed?**

Yes Begin application No Continue to Step 4 prior to application

Wound bed depth <0.5cm

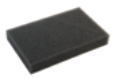
Wounds >0.5cm in depth are likely to require a foam or gauze NPWT filler. Appropriate for wounds up to 4.5cm.



## Step 4 Fillers

Antimicrobial gauze 15cm x 17cm

**Note:** Gauze should loosely fill to the surface of the wound. Avoid overpacking.



Foam dressing 10cm x 12.5cm

**Note:** Please refer to the IFU for information regarding possible tissue ingrowth when using foam filler.

## Wear instructions:

- The frequency of dressing changes can be affected by multiple factors such as wound type, wound size, rate or volume of exudate, orientation, or environmental conditions. Additional dressings are available to purchase separately, as required.
- At the healthcare professional's discretion, a PICO dressing may be left in place for up to 7 days, depending on level of exudate.
- When a filler is used, the filler and the PICO dressing should be changed 2 to 3 times a week, according to the local clinical protocol and manufacturer's instructions.
- Foam should be changed at least 3 times per week and gauze at least 2 times per week.
- Indication: PICO 7 and PICO 14 can be used in combination with Graduated Compression Therapy in the management of Venous Leg Ulcers.

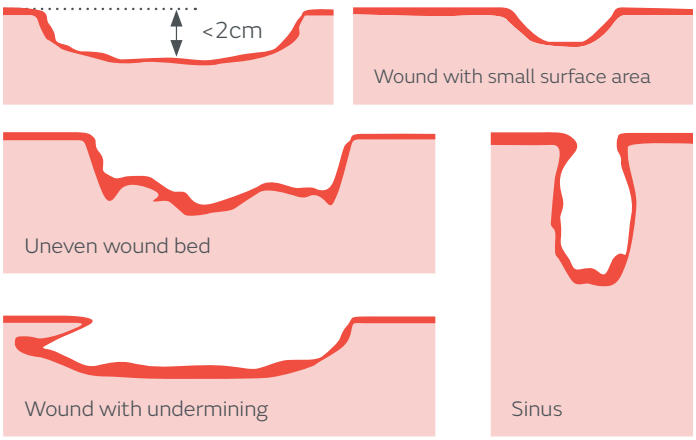
# Simple guidance for using the PICO◊ System with wound fillers

## PICO dressings can be used with or without fillers

If the wound depth is under 0.5cm the PICO dressing can be applied directly to the wound. If the wound is greater than 0.5cm in depth a NPWT filler is likely to be required.

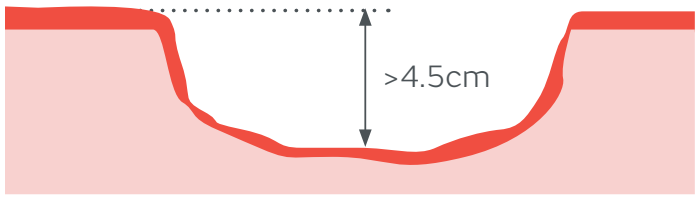
**Hint:** When applying PICO dressings without a filler gently use fingers to help conform dressing to the wound

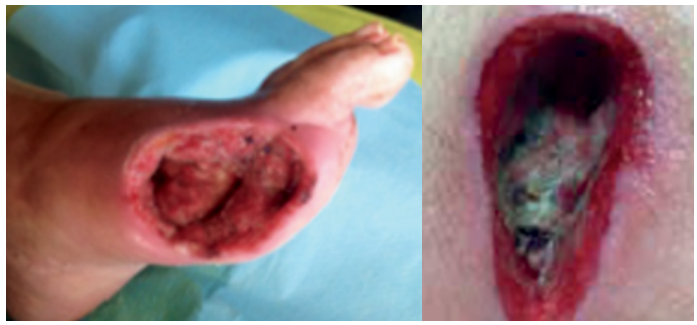
Wounds types under 2cm that the use of a filler would be appropriate:




## NPWT wound fillers

Wounds between 2cm and 4.5cm with the PICO System **must** be treated with a gauze or foam wound filler with the PICO System to ensure adequate treatment of all the wound surface.†



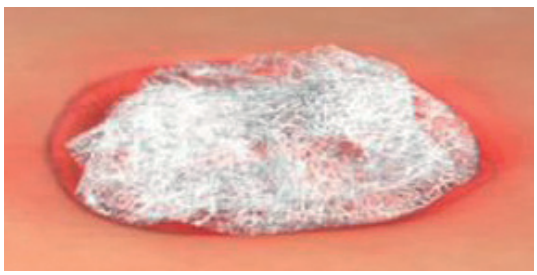



Examples of deeper wounds

†Wounds should generally be no more than 4.5cmin depth and must not contain exposed arteries, veins, nerves or organs.

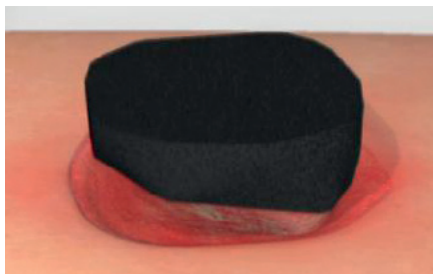
## Application of the NPWT wound filler

### Gauze filler



- Apply layer of saline-moistened gauze to wound bed. Continue to apply in layers until the gauze loosely fills the entire wound cavity
- Avoid overpacking the wound cavity
- Ensure the gauze is not overlapping onto the peri wound area

### Foam filler



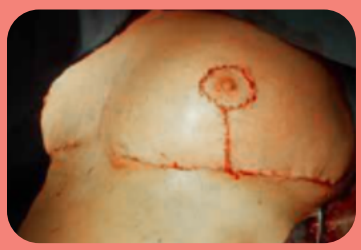
- Cut the foam to fit the size and shape
- Do NOT cut the foam directly over the wound
- Ensure the foam is not overlapping onto the peri wound area

## Selection guidance: closed surgical incisions

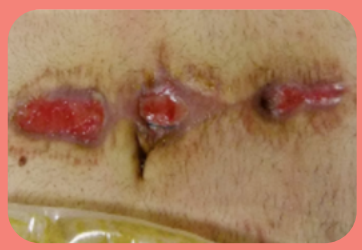
The PICO◊ Systems are indicated for use on closed surgical incisions, to aid in reducing the incidence of:

- Superficial and deep incisional surgical site infections for high-risk patients (Class I and II wounds)
- Post-operative seroma
- Dehiscence

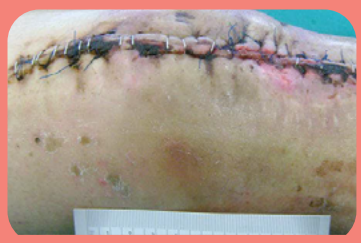
### Examples of appropriate incisions



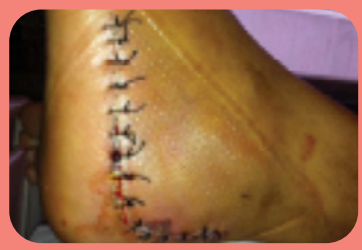
**Breast surgery**



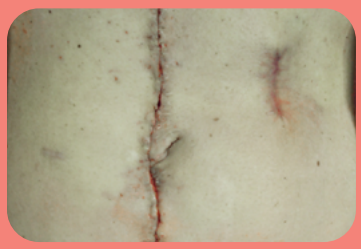
**Colorectal surgery**



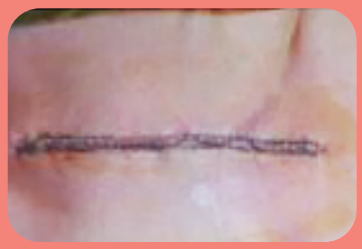
**Hip or knee surgery**



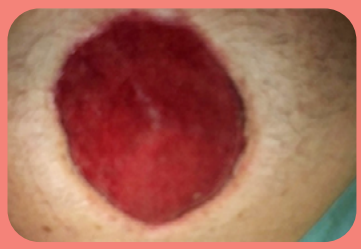
**Calcaneal surgery**



**Abdominal/ C-section surgery**



**Coronary artery bypass graft surgery**



**Skin grafts**

## Is your patient high risk?

Multi-morbid patients with common risk factors are more susceptible to developing SSCs, which can have significant real-world impacts[47–49]

### BMI ≥ 40

Significantly more likely to suffer **prolonged drainage** following THA*[50]

### BMI ≥ 35

**4.5x** times more likely to suffer an **SSC** following TKA or THA surgery†[51]

### ASA ≥ 3

**8x** times more likely to suffer an **SSC** following TKA or THA surgery†[51]

### Operative time

**SSI risk** increases by **11%** every 15 minutes during TKA§[52]

### Revision

**Deep or organ space SSI** can nearly **quadruple** with revision hip arthroplasty compared with primary procedures[53]

### Emergency

Up to **16%** SSI rate following peri-prosthetic hip fracture[54,55]

*Compared with normal weight; p = 0.001. †Compared with BMI < 35. ‡Compared with patients with ASA < 3. §Where operative times had a significant independent effect on SSI rates (adjusted OR 1.007, 95% CI 1.004-1.011, P < .001;) which corresponded to an 11% (95% CI 6-17) increase in SSI risk with every 15-minute increase in operative time.

## Closed surgical incision management pathway: when to use PICO◊ sNPWT

Identify patients at risk of SSCs during pre-operative risk assessment:[28,56]

**Major risk factor:**
Presence of 1 = high risk of SSC

**Moderate risk factor:**
Presence of ≥2 = high risk of SSC

| Patient-related risk factor | Procedure-related risk factor |
|---|---|
| BMI≥40 | Emergency surgery |
| Untreated insulin-dependent diabetes | Extended surgery time |
| Renal dialysis | Hypothermia |
| ASA physical status >II | Anemia/blood transfusion |
| BMI 30–39.9kg/m$^2$ | Dual antiplatelet treatment |
| Immunosuppression | Suboptimal timing or omission of prophylactic antibiotics |
| Smoker (current) | Tissue trauma/large area of dissection/large area of undermining |

**AT RISK** *of SSC* → Consider use of PICO sNPWT

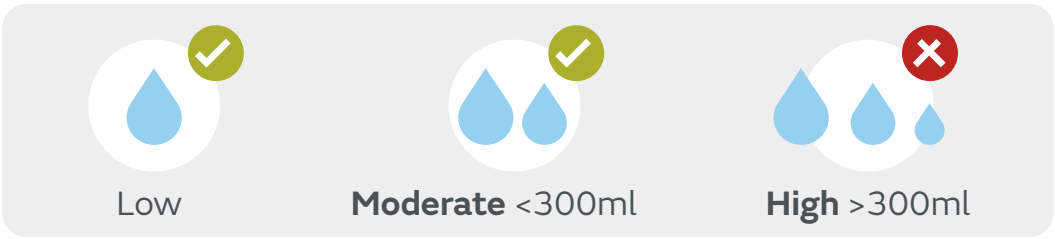
**LOW RISK** *of SSC* → Use standard surgical dressing

*The presence of just* **1 major risk factor or 2 or more moderate risk factors** *places patients at high risk of SSCs and means you should consider PICO sNPWT*[28]

## Simple tips to support applying the PICO◊ System over closed surgical incisions

### Step 1 Exudate levels

**Does the wound have low to moderate levels of exudate?**




Yes Continue to Step 2

No Not appropriate

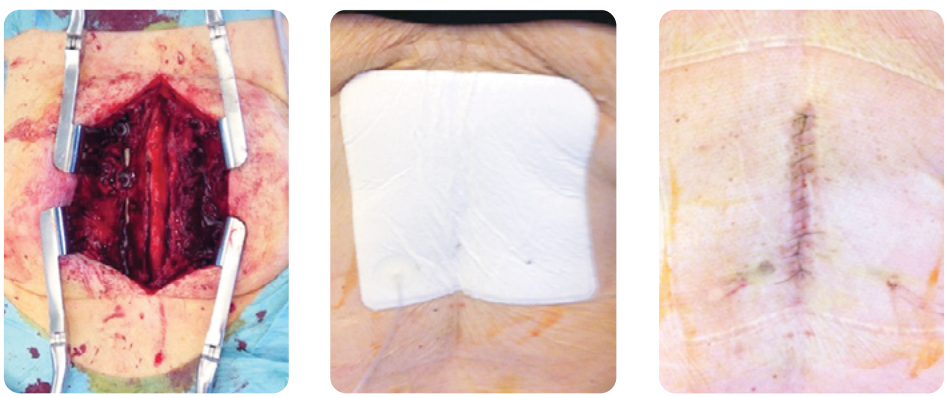
### Step 2 Incision length

**Choose from one of 8 dressing sizes**


### Step 3 Consider the zone of injury

**Do you need to consider a larger dressing?**

The underlying tissue is damaged during surgery but the PICO dressing can be placed over the entire zone of injury. This means you are not only treating the incision but the surrounding tissue around the incision.[28]

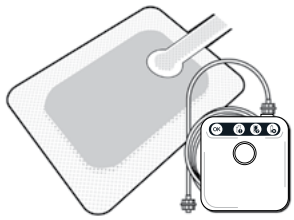


Clinical images provided courtesy of Dr. Mattias Brem

## Step-by-step product application and dressing change guidance

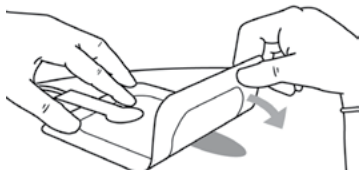
### Prep

1. Clean and prepare wound according to local protocol.

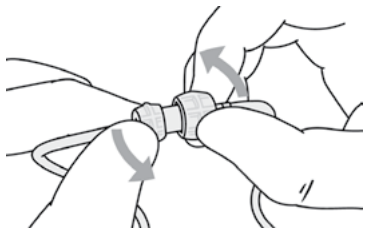


### Dress

2. Peel off the first release handle and place the dressing centrally over the wound. The dressing should be applied with the soft port positioned higher than the wound (depending on the patient's primary position), placed on intact skin and not extending over the wound to prevent fluid pooling around the soft port and blocking the therapy.

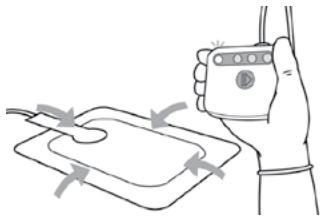


3. Remove the other remaining handle(s) and smooth the dressing around the wound to prevent creasing. Reposition if required to ensure border is not creased.



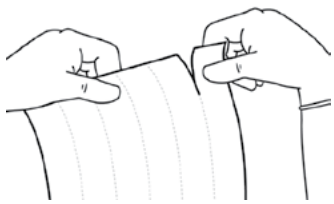
### Press

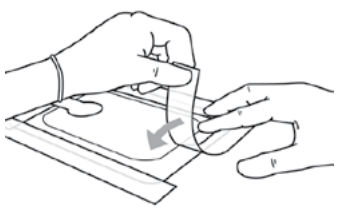
4. Insert the batteries into the device.
5. Join the pump to the dressing by twisting together the tubing connectors. Extension tubing can be added if required.
6. Press the orange button to start the application of negative pressure. The green 'OK' indicator and the orange air 'leak' indicator will flash together while working to establish therapy. The 'OK' green light will start to flash after about 100 seconds to indicate therapy is established.



### Go

7. Apply the fixation strips to each of the four sides of the dressing.
8. The pump device has a 14-day life for PICO◊ 14 and a 7-day life for PICO 7 System.
9. The dressing may be left in place for up to 7 days depending on the level of exudate.
10. When a filler is used, the filler and the PICO dressing should be changed 2 to 3 times a week.





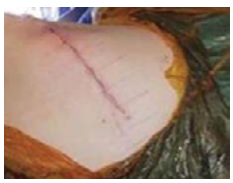

PICO application tips and tricks video

PICO application video

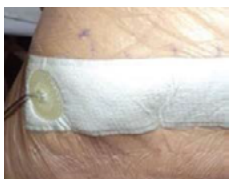
# Practical applications of the PICO◊ System

## Joint surgery

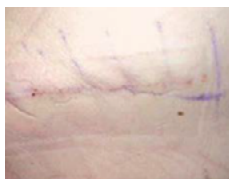
- **Exudation:** low/moderate
- The PICO 7 or PICO 14 System may be an appropriate option for joint procedures
- PICO dressings may be applied over incisions closed with a variety of methods: Sutures, staples, skin glues, or other surgical skin closures
- Remove excess hair and use NO STING SKIN-PREP◊ Skin Protectant if needed
- When applying over a curved area such as an elbow or knee, flex the joint 15–30 degrees to prevent tension on the skin and allow for range of motion
- Port position: uppermost from incision
- Fixation strips (included in kit) will help maintain a seal
- Dressing may be left in place for up to 7 days. The PICO 14 Pump will continue therapy for 14 days
- ACTICOAT◊ FLEX may be applied in conjunction with the PICO dressing
- If using ACTICOAT FLEX, dressing should be changed 2–3 times per week



Post-op total hip replacement

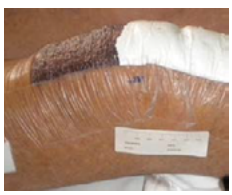


PICO System in situ

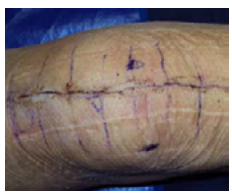


Post-op day 9

Day 0: Application of the PICO System in the OR



Exudate management at 72 hours

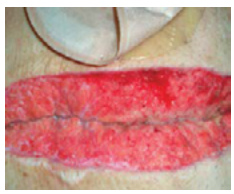


Follow-up at 72 hours

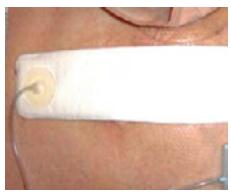
**Commonly used dressing sizes:**
10x20cm, 10x30cm, 10x40cm
Individual results will vary

## Dehiscence

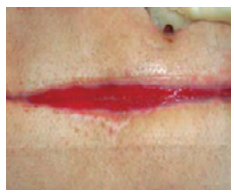
- **Exudation:** low/moderate
- Remove excess hair and use NO STING SKIN-PREP◊ Skin Protectant if needed
- For wounds 0.5cm–4.5cm deep, a filler may be required
- **Fillers:** ACTICOAT◊ FLEX, foam, gauze
- Choosing a dressing size slightly larger than the wound extends the benefit of negative pressure to the periwound area
- Port position: uppermost from wound
- Therapy may be applied for 7 or 14 days with the PICO 7 or 14 System
- When a filler is used, dressing should be changed 2–3 times per week
- Dressing may be applied post-operatively in the hospital, at home or in office setting



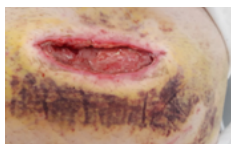
14 days post-op and following 10 days of RENASYS◊ NPWT



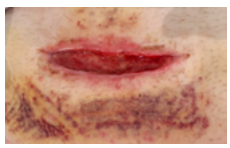
PICO System in situ at the commencement of treatment



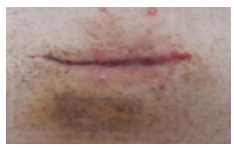
Day 22 of PICO treatment, 35 days post-op



Prior to application of PICO dressing



Following 2 weeks treatment of PICO therapy

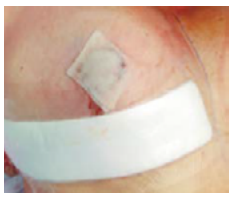


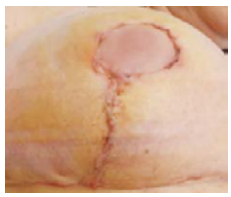
Healed after 4 weeks

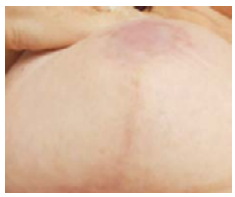
**Commonly used dressing sizes:**
10x30cm, 15x30cm
Individual results will vary

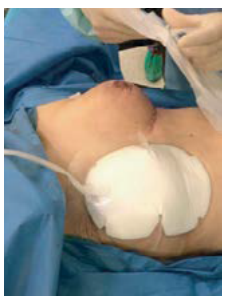
## Breast

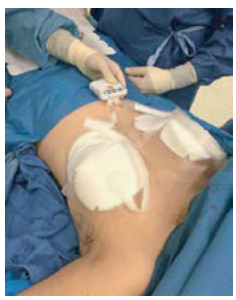
- **Exudation:** low/moderate
- More than 1 PICO◊ System may be used if there is more than 1 incision. The **PICO 7Y System**, which treats two incisions may be used. (1 pump connected to 2 dressings)
- PICO System may be used in conjunction with surgical drains provided the dressing is not placed over tubing where it exits the skin. The silicon border may be trimmed if needed for drain placement.
- Remove excess hair and use NO STING Skin Protectant if needed
- Port position: uppermost from incision
- In areas of complexity, fixation strips or gel strips* (*not included in kit) may be used to maintain a seal
- Dressing may be left in place up to 7 days
- The PICO 7Y System can be used in conjunction with adjuvant Pressure Garment Therapy (PGT), such as hosiery or elastic garments following surgery (including breast surgery)

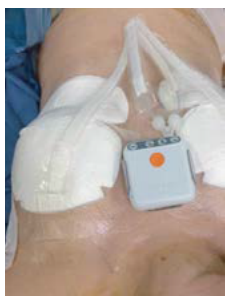

PICO System in situ

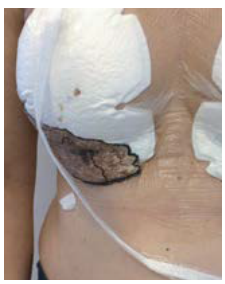

Day 7

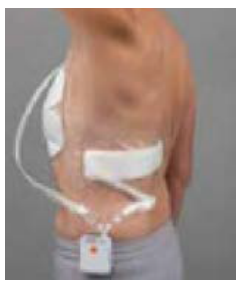

Day 22: 35 days post-op









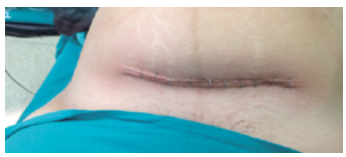


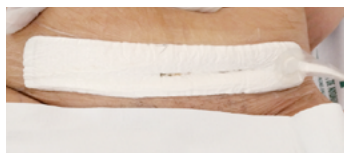
The PICO 7Y System application

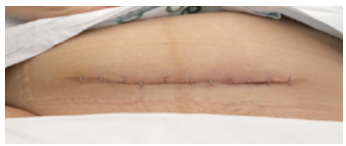
**Commonly used dressing sizes:**
10x20cm, 10x30cm, PICO 7Y System
Individual results will vary

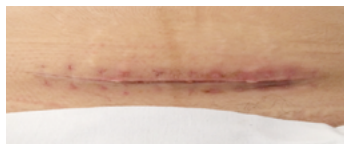
## C-sections

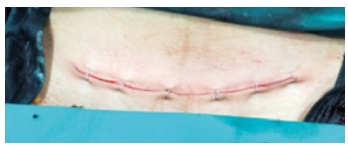
- **Exudation:** low/moderate
- Remove excess hair and use NO STING SKIN-PREP◊ Skin Protectant if needed
- In areas of complexity, fixation strips or gel strips* (*not included in kit) may be used to maintain a seal
- Dressing may be left in place up to 7 days
- To aid in the healing process, ACTICOAT◊ FLEX may be applied in conjunction with PICO sNPWT (Consider for higher-risk patient protocols)
- If using ACTICOAT FLEX, dressing should be changed 2–3 times per week
- Improved scar appearance vs standard dressings*


Day 0: Application of the PICO System in the OR

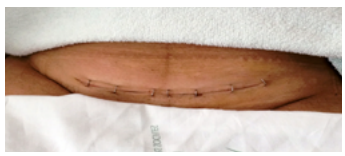

Exudate management at 72 hours

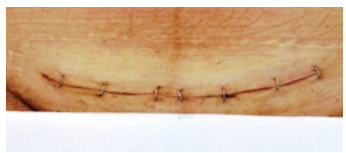

Follow-up at 72 hours


Removal of the PICO System during follow-up at 7 days


Day 0: Application of the PICO System in the OR


Exudate management at 72 hours


Follow-up at 72 hours

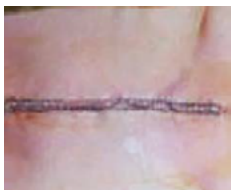

Removal of the PICO System during follow-up at 7 days

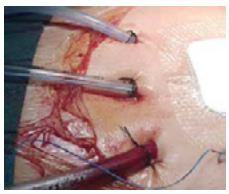
*Women who received PICO sNPWT following a C-section were more satisfied with the overall cosmetic appearance of the scar at 30 days and six months

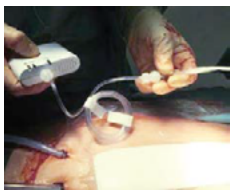
**Commonly used dressing sizes:**
10x30cm, 10x40cm, 15x30cm
Individual results will vary

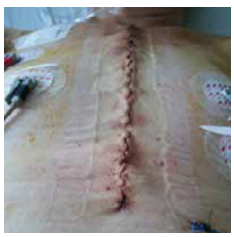
## Coronary artery bypass graft procedures

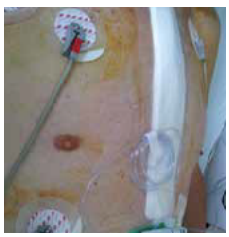
- **Exudation:** low/moderate
- Remove excess hair and use NO STING SKIN-PREP◊ Skin Protectant if needed
- PICO◊ System may be used in conjunction with surgical drains provided the dressing is not placed over tubing where it exits the skin
- Place dressing approximately 1 inch above the drains
- Port position: uppermost from incision
- In areas of complexity, fixation strips or gel strips* (*not included in kit) may be used to maintain a seal
- Therapy may be applied for 7 or 14 days with the PICO 7 or 14 System

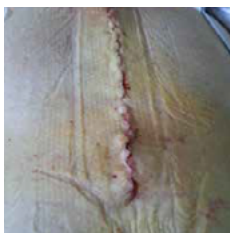

Sternal incision after closure


PICO System proximity to drains


PICO System in situ


Day 0: Initial incisional line

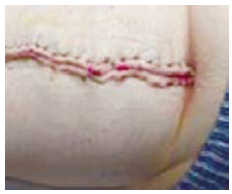

Day 0: PICO System in situ

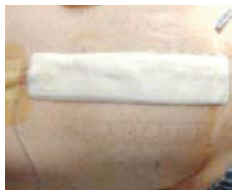

Day 5: After the first dressing change

**Commonly used dressing sizes:**
10x20cm, 10x30cm, 10x40cm
Individual results will vary

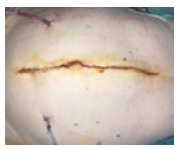
## General, colorectal, vascular surgery

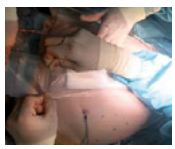
- **Exudation:** low/moderate
- The PICO 7 or PICO 14 System may be appropriate for these procedures
- The PICO System may be used in conjunction with surgical drains provided the dressing is not placed over tubing where it exits the skin
- Remove excess hair and use NO STING SKIN-PREP◊ Skin Protectant if needed
- For wounds 0.5cm–4.5cm deep, a filler may be required
- **Fillers:** ACTICOAT◊ FLEX, foam, gauze
- Do not place gauze into blind or unexplored tunnels
- Do not use over exposed arteries, veins, nerves or organs
- Port position: uppermost from incision
- In areas of complexity, fixation strips or gel strips* (*not included in kit) may be used to maintain a seal
- Dressing may be left in place for up to 7 days. The PICO 14 Pump will continue therapy for 14 days.

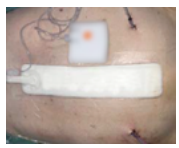

Post-op colorectal incision

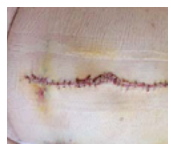

PICO System in situ


Post-op day 7


Day 0: Surgical wound closure


Day 0: Application of the PICO System in the OR

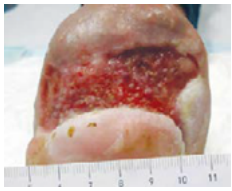

Drain removal from the surgical wound


Day 7: End of PICO System application

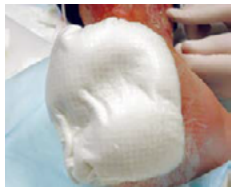
**Commonly used dressing sizes:**
10x20cm, 10x30cm, 10x40cm
Individual results will vary

## Lower extremity wounds

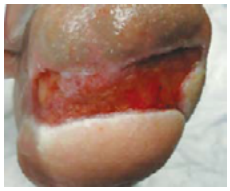
- **Exudation:** low/moderate
- Remove excess hair and use NO STING SKIN-PREP◊ Skin Protectant if needed
- For wounds 0.5cm–4.5cm deep, a filler may be required
- **Fillers:** ACTICOAT◊ FLEX, foam, gauze
- Port position: uppermost from wound
- In awkward areas, fixation strips and gel strips* (*not included in kit) may be used to maintain a seal
- Indicated to be used in combination with graduated compression therapy in the management of venous leg ulcers
- Dressing may be left in place up to 7 days
- When a filler is used, dressing should be changed 2–3 times per week
- Can be used to wound closure



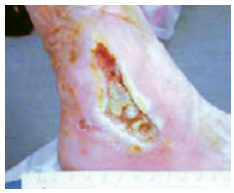
Wound prior to PICO◊ System therapy



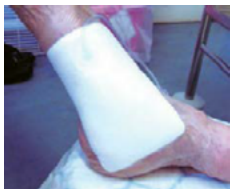
PICO System application



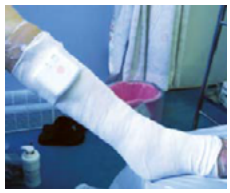
Wound after 2 weeks of PICO System therapy.



Wound prior to the commencement of PICO System



The application of PICO System



The application of PICO System and PROFORE◊ Multi-Layer Compression Bandaging System

**Commonly used dressing sizes:**
15x15cm, 15x20cm, 15x30cm, 20x20cm, 10x20cm

Individual results will vary

## Additional application guidance

- PICO◊ sNPWT should only be applied by a healthcare professional.
- Do not use the PICO dressing with oil-based products; seal may be compromised.
- Do not alter or cut tubing or dressing for application.
- To achieve a proper seal, remove excess hair from the application site and ensure periwound is completely dry.
- If applying in areas of complexity (i.e., skin folds, digits, contours), use of a gel strip or other wound care products may be used to create a tight seal. Adhesive strips may be needed to seal difficult areas.
- **PICO dressings may be applied over incisions closed with: sutures, staples, skin glues, or other surgical skin closures.**
- **When applying the dressing, be sure to place the dressing without stretching it over the skin, as this may cause blistering.**
- When applying over a joint, flex the joint 15–30 degrees to prevent tension on the skin and allow for proper range of motion.
- The PICO System can be used in conjunction with surgical drains, provided the dressing is not placed over tubing where it exits the skin, place approximately 1in from drain (silicone border may be cut around drain).
- Wounds greater than 4.5cm in depth may require a foam or gauze filler to ensure adequate treatment. As with all NPWT devices, it is important that there is intimate contact with all areas of the wound bed to ensure that NPWT will be delivered.
- The PICO System may be used in conjunction with graduated compression therapy for the management of VLUs.
- Only air is pushed through the tubing; a filter prevents fluid from coming back through the tubing.
- Upon application, patients may feel a slight pulling or drawing sensation.
- 'Leak' indicator light illuminates: smooth down the dressing to remove any creases. Make sure the tube connectors are twisted together securely and tighten if needed.
- The dressing has a wear time of up to 7 days, depending on exudate levels.
- When using a filler the PICO dressing must be changed every 3-4 days.
- **Light showering is permissible:** disconnect pump, hold tubing facing downward, do not submerge in water.

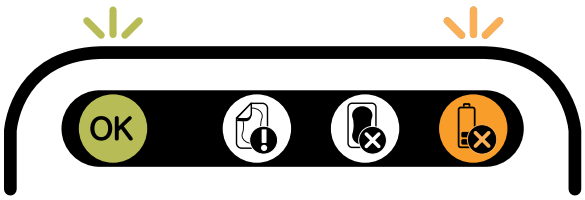
**For additional application tips and tricks**

## Maintaining pump functionality

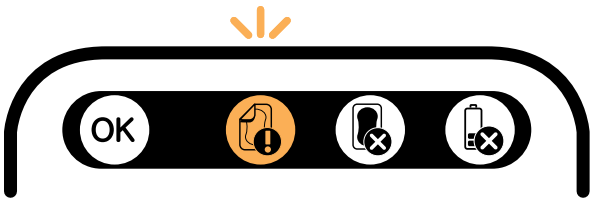
The PICO◊ System has visual indicators to let the user know when there is an issue. The PICO System does not contain audible alerts. The pump should be carried so that it is accessible, and the patient/healthcare professional can check the status routinely in case there is a fault or in case of damage.

## Pump light indicators

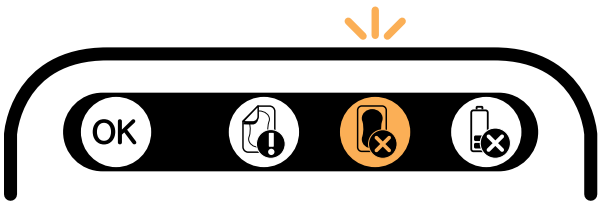
### PICO Pump




Flashing **green 'OK' indicator** and **orange 'battery low' indicator** together = **battery needs changing.**



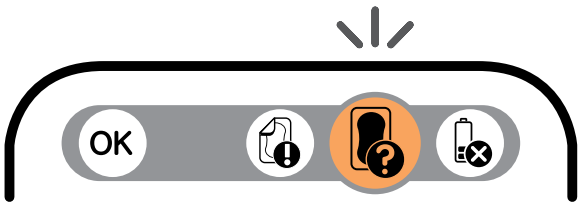

Flashing **orange 'leak' indicator** = **air leak detected.** You will hear the pump make a buzzing sound as it tries to reestablish a seal.

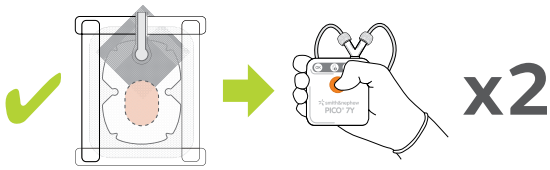



Flashing **orange 'dressing full' indicator** = **dressing saturated** or the port is **blocked**.

### PICO 7Y System

- Orange 'check dressing' light flashes
- When this indicator flashes, the condition of the dressings needs to be checked.




If no dressing change is required by a healthcare professional, refresh the device by pressing the orange button twice.

# Frequently asked questions

## Device operation

### *What is the machine's suction pressure?*

The PICO◊ System maintains continuous negative pressure of -80mmHg.

### *Is the pressure preset?*

Yes, at -80mmHg and is non-adjustable.

### *Does it have an Intermittent feature?*

No. For intermittent therapy, consider traditional NPWT.

## Maintenance and handling

### *When to change the canister?*

There is no canister. For fluid over 300cc/week, traditional NPWT is recommended.

### *How do I clean the machine?*

Wipe with a damp cloth and soapy water or a mild disinfectant, adhering to clinical hygiene guidelines.

### *Proper Disposable*

The PICO dressing and fixation strips should be disposed of as clinical waste in accordance with local protocol. The batteries should be removed from the pump; and both batteries and pump disposed of according to local regulations.

## Usage guidelines

### *Can patients shower with the PICO System?*

Yes, with precautions:

- The pump should be disconnected and placed in a location where it will not get wet.
- Do not directly expose the dressing to a direct spray of water or submerge the dressing in water.
- Ensure the end of the tubing attached to the dressing is facing down, or covered, to prevent water entry.

### *Is there a valve to prevent fluid backflow?*

Yes, a filter is in place in the tubing to prevent this.

### *Can you "Y" wounds together and if so, how many?*

The PICO 7Y System is available for use, which includes a "Y" connector and 2 Multisite-size dressings.

## Battery and portability

### *Battery lifespan?*

The System runs on two AA batteries that can be changed out if required, but replacements are generally unnecessary as it is indicated for up to 7 days for the PICO 7 and 7Y, and 14 days for PICO 14 Systems.

### *Machine weight?*

The PICO System weighs less than 4.2oz and is small enough to be placed on a pocket or a waistband utilizing the belt clip included with kit.

## Dressing and wound management

### *What is the interface with the wound?*

PICO◊ sNPWT uses an innovative, proprietary dressing that manages exudate via absorption and evaporation, removing the need for canisters.

### *Dressing change frequency?*

The PICO 7 System may be left in place for up to 7 days, while the PICO 14 System will provide therapy for 14 days. Please note dressing change is required at day 7, or earlier based on exudate levels, upon health care professional clinical judgment. If a wound filler is used with PICO dressing, refer to filler guidelines. ACTICOAT◊ FLEX 3 and ACTICOAT FLEX 7 are only approved for use with NPWT for up to 3 days.

### *How to manage exposed tendon or bone?*

Cover with natural tissue or a non-adherent layer before applying the NPWT dressing.

### *Recommendations for high bioburden or infection?*

If available, use Smith+Nephew ACTICOAT FLEX as a wound contact layer. ACTICOAT FLEX is compatible for use with gauze or foam and indicated for use with the PICO System.

**Note:** Wounds that are infected may require more frequent dressing changes. Conduct wound bed preparation and debridement before NPWT.

# Appendix


RENASYS TOUCH


RENASYS EDGE


PICO Systems

# Evidence-base and clinical case studies for the PICO◊ System

**PICO Single Use Negative Pressure Wound Therapy (sNPWT) has a strong evidence base.**

To date, **316*** clinical publications (peer-reviewed manuscripts and conference abstracts) regarding PICO sNPWT have been identified (166 unique studies). This evidence compendium contains summaries of the most relevant publications; it does not include all the publications due to the volume of studies.

## Levels of evidence


**60**

RCTs, meta-analyses, health economics evaluations of RCTs


**19**

Prospective comparative observational studies


**35**

Retrospective comparative observational studies


**62**

Case series and case studies


**90**

Expert opinion, case studies or bench research

(**+50** studies that note PICO sNPWT studies)

## To access our PICO System clinical evidence please scan the QR codes below

**Closed incisions**

**Open wounds**

**Patient resources**

# PICO◊ System ordering information

| Product Codes | | | | | |
|---|---|---|---|---|---|
| 2x Dressing Kit* | 1x Dressing Kit** | Fluid Management Packs*** | PICO 14 System | Dressing size | Pad size |
| 66022002 | 66022012 | 66022022 | 66022042 | 10cm x 20cm | 5.6cm x 15cm |
| 66022003 | 66022013 | 66022023 | 66022043 | 10cm x 30cm | 5.6cm x 25cm |
| 66022004 | 66022014 | 66022024 | 66022044 | 10cm x 40cm | 5.6cm x 35cm |
| 66022005 | 66022015 | 66022025 | 66022045 | 15cm x 15cm | 10cm x 10cm |
| 66022006 | 66022016 | 66022026 | 66022046 | 15cm x 20cm | 10cm x 15cm |
| 66022007 | 66022017 | 66022027 | 66022047 | 15cm x 30cm | 10cm x 25cm |
| 66022008 | 66022018 | 66022028 | 66022048 | 20cm x 20cm | 15cm x 15cm |
| 66022009 | 66022019 | 66022029 | 66022049 | 25cm x 25cm | 20cm x 20cm |
| 66022031 | PICO 7Y System with Multisite Dressings | | | | |
| 66801691 | PHMB gauze filler 15cm x 17cm | | | | |
| 66801692 | Foam dressing filler 10cm x 12.5cm x 1.25cm | | | | |
| 66801082 | RENASYS◊ Adhesive Gel Patch | | | | |

*2 dressings + 1 pump;

**1 dressing + 1 pump;

***5 dressings only

**Important Safety Information:** The PICO pumps contain a MAGNET. Keep the PICO pumps at least 4 inches (10cm ) away from other medical devices at all times. As with all electrical medical equipment, failure to maintain appropriate distance may disrupt the operation of nearby medical devices. For full product and safety information, please see the Instructions for Use.

# RENASYS◊ System ordering information

| Order no. | Description (Unit) ** | Units/case |
|---|---|---|
| **RENASYS tNPWT** (1 Pump = 1 Unit) | | |
| 66802134 | **RENASYS TOUCH Pump** | 1 |
| 66803126 | **RENASYS EDGE Pump** | 1 |
| **Dressings** (1 Kit = 1 Unit) | Each kit includes Filler (foam or gauze), Soft Port◊, and Transparent Film | |
| 66020794 | **RENASYS-F, Foam Dressing Kit, Small**<br>• Foam block 10cm x 8cm x 3cm<br>• RENASYS Transparent Film<br>• RENASYS Soft Port | 5 |
| 66020795 | **RENASYS-F, Foam Dressing Kit, Medium**<br>• Foam block 20cm x 12.5cm x 3cm<br>• 2 RENASYS Transparent Films<br>• RENASYS Soft Port | 5 |
| 66020796 | **RENASYS-F, Foam Dressing Kit, Large**<br>• Foam block 25cm x 15cm x 3cm<br>• 3 RENASYS Transparent Films<br>• RENASYS Soft Port | 5 |
| 66020797 | **RENASYS F, Foam Kit, X-LARGE**<br>• 1 Foam block 48cm x 41cm x 1.5cm<br>• 6 RENASYS Transparent Film-Large 20cm x 30cm<br>• 1 RENASYS Soft Port | 5 |
| 66021980 | **RENASYS-AB, Abdominal Dressing Kit**<br>• 2 Foam blocks 40.5cm x 27.5cm x 2.5cm<br>• Organ protection layer 80cm x 66cm<br>• 6 RENASYS Transparent Films<br>• RENASYS Soft Port | 5 |
| 66020933 | **RENASYS-G, Gauze Dressing Kit, Small**<br>• AMD Gauze Dressing 15cm x 17cm<br>• RENASYS Transparent Film<br>• RENASYS Non-adherent gauze<br>• RENASYS Soft Port<br>• SECURA◊ No-Sting Barrier Film wipe<br>• Saline<br>• Paper ruler | 5 |
| 66020934 | **RENASYS-G, Gauze Dressing Kit, Medium**<br>• AMD Gauze Dressings 15cm x 17cm<br>• RENASYS Transparent Film<br>• RENASYS Non-adherent gauze<br>• RENASYS Soft Port<br>• SECURA No-Sting Barrier Film wipe<br>• Saline<br>• Paper ruler | 5 |
| 66020935 | **RENASYS-G, Gauze Dressing Kit, Large**<br>• AMD Gauze Roll 11.4cm x 3.7m<br>• 2 RENASYS Transparent Films<br>• 2 RENASYS Non-adherent gauzes<br>• RENASYS Soft Port<br>• SECURA No-Sting Barrier Film wipe<br>• Saline<br>• Paper ruler | 5 |

| Order no. | Description (Unit) ** | Units/case |
|---|---|---|
| **Canisters** (Includes Canister and Tubing, 1 Canister = 1 Unit) | | |
| 66801273 | RENASYS TOUCH 300mL canister w/ solidifier | 5 |
| 66801275 | RENASYS TOUCH 300mL canister w/out solidifier | 5 |
| 66801274 | RENASYS TOUCH 800mL canister with solidifier | 5 |
| 66801271 | RENASYS TOUCH 800mL canister w/out solidifier | 5 |
| 66803139 | RENASYS EDGE 300 ml Canister with Solidifier | 5 |
| **Accessories** | | |
| 66801278 | RENASYS TOUCH IV Pole/Bed Clamp | 1 |
| 66800394 | RENASYS Transparent Film (20cmx30cm, 1 pouch of 10 films per unit) | 10 |
| 66020853 | RENASYS Transparent Film - X LARGE (38cm x 60 cm , 1 pouch of 5 films per unit) | 5 |
| 66801082 | RENASYS Adhesive Gel Patch (1 carton of 10 patches per unit) | 5 |
| 66027659 | RENASYS WF, White Foam Small – 7.5cm x 10cm x 1cm | 10 |
| 66027660 | RENASYS WF, White Foam Large – 10cm x 15cm x 1cm | 10 |
| 66801692 | Foam Wound Dressing | 5 |
| 66020971 | RENASYS Y-Connector | 10 |
| 66020799 | RENASYS Soft Port | 5 |
| 66800391 | NPWT Antimicrobial Large Gauze Roll (1 wipe and 5 rolls per unit) | 10 |
| 66801691 | Antimicrobial Gauze | 10 |
| 66801286 | RENASYS TOUCH Class 2 Power Supply (connects to pump) | 1 |
| 66801564 | RENASYS Power Cord Class 2 (connects to wall) | 1 |
| 66803146 | RENASYS EDGE Plug-in Main Adapter | 1 |
| 66801283 | TOUCH O-ring (20 rings per unit) | 20 |
| 66801284 | Odor filter (20 filters per unit) | 20 |
| 66801276 | RENASYS TOUCH Carry Straps | 1 |
| 66801277 | RENASYS TOUCH Carry Bag | 1 |
| 66803136 | RENASYS EDGE Carry Bag | 1 |
| 66803137 | RENASYS EDGE Carry Straps | 1 |
| 66027646 | RENASYS TOUCH Service Manual (compatible with 66801281 and 66802134) | 1 |
| 66020801 | RENASYS TOUCH Clinician Manual (Included) | 1 |
| 66803143 | RENASYS EDGE Clinician Manual | 1 |
| 66803144 | RENASYS EDGE Homecare Manual | 1 |

# Contact information for support

## Customer Care:

**Find out more about the PICO Systems:**

**Visit our YouTube channel:**

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Smith+Nephew

Please see the instructions for use (IFU) for indications, contraindications, warnings and precautions and other important safety information.

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