Negative Pressure Wound Therapy Clinical Guidelines
Consult your local Smith & Nephew representative if you have any questions about operation or use. Information on RENASYS™ or PICO™ devices can be found in the user device manual or on the web at www.myrenasys.com or www.possiblewithpico.com

These guidelines are recommendations to help clinicians to establish condition-specific treatment guidelines when using NPWT as part of the treatment protocol. Please consult the patient’s primary physician or clinician about individual conditions and treatment. These guidelines are not intended as a guarantee of results, outcome or performance of NPWT.
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Negative pressure Wound Therapy (NPWT) is an established therapy that has changed the way serious wounds are treated. Smith & Nephew has been involved in wound care since 1856. As global provider of wound care solutions, Smith & Nephew is known for providing innovative enhancements and greater options for NPWT use, and for placing the option for NPWT use within a broader continuum of care.

Smith & Nephew has an extensive portfolio in wound care and therapies that cover all of its major aspects. The concept is well established that wounds are managed across a continuum of healing and require different therapies at each step in the continuum. NPWT is no exception. Smith & Nephew offers NPWT as part of a complete range of wound care products to use along the patients’ journey towards healing. The key to deciding which product to use at each stage of the continuum is to identify the barriers to healing and a treatment goal to combat those issues. The treatment goal can be a variety of steps along the wound healing continuum such as to control infection or generate a healthy granulating wound bed. Different products are appropriate to address different treatment goals and the correct product choice is necessary not only to achieve positive outcomes, but to also provide efficient use of resources.

When NPWT was initially introduced it was reserved for use on the most complex wounds. Today, however, NPWT is widely adopted as a standard treatment for patients with both acute and chronic wounds. A variety of formats are now available, and, as the wound progresses along the continuum, a switch from one format to another may be the most appropriate course. NPWT has been shown to be cost effective when used appropriately. However, it is important to guard against over-use of NPWT in order to maintain these health economic benefits. Knowledge of when NPWT is most appropriate and when alternative therapies may be more appropriate is vitally important to maintain an efficient use of resources while not effecting wound outcomes negatively.

Negative Pressure Wound Therapy (NPWT) involves the application of controlled levels of sub-atmospheric (negative) pressure to a wound. The systems described in these guidelines consist of a suction pump to generate negative pressure and a variety of wound dressing kits to deliver the therapy to the wound site.

The benefits of NPWT go well beyond drainage management. Studies have shown NPWT improves granulation tissue formation, may decrease bacterial burden, protects from the outside environment, promotes moisture balance within the wound bed, and may decrease the frequency of dressing changes.1

The following Clinical Guidelines are meant to be used as recommendations for treating specific wound types. The Guidelines cannot guarantee positive outcomes, wound healing or proper function of the Smith & Nephew NPWT device. As with any medical device, consult the physician/clinician concerning the patient’s individual condition and prescribed treatment. Always consult and follow all applicable user manuals, product inserts, instructions for use, safety information and references guides for product use, operation and application.

The purpose of this document is to describe the most appropriate use of NPWT as an integral part of wound bed preparation to ensure optimal healing and cost-effective wound care.
Wound bed preparation

Wound bed preparation has been defined as the process of removing the barriers to healing. Removal of these barriers is thought to allow the wound repair process to progress normally. Wound bed preparation represents a combination of both scientific knowledge and practical skill; its application can help correct abnormalities in acute and chronic wounds and stimulate or progress the healing process. To optimize the use of NPWT, it is essential that clinicians ensure wound bed preparation is achieved prior to, during and after therapy.

1. Debride wound
   
   **Effective debridement may:**
   - Reveal extent of tissue damage
   - Reduce biochemical imbalance, senescent cells
   - Reduce bacterial burden
   - Reduce odor
   - Optimize healing potential

   **Consequences of ineffective debridement are:**
   - Delayed healing
   - Potential for infection
   - Physical barrier preventing accurate assessment
   - Reduced patient Quality of Life (QoL)
   - Psychological aspects

2. Optimize healing
   
   - Remove excess fluid edema
   - Assist in wound contraction
   - Stimulate granulation tissue
   - Protect from outside contaminants
   - Increase vascular perfusion
   - May reduce wound bioburden
   - Remodel connective tissue matrix
   - Encourage maturation of epithelial cells
   - Maintain a moist wound healing environment

3. Know when to stop or change treatment
   
   - Initial therapy objectives have been met
   - 100% granulation tissue in the wound bed
   - Granulation tissue level with the surrounding skin
   - Patient's overall condition/wound is improving
   - Wound bed ready to take a skin graft/flap
   - Exudate levels less than 20–50mLs per day
   - No improvement/reduction in size is seen in the wound bed following two consecutive dressing changes

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**Optimal healing/cost-effective wound care**
Indications for use

The RENASYS system is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing by removing fluids, including irrigation and body fluids, wound exudates and infectious materials.

Examples of appropriate wound types include:
- Chronic
- Acute
- Traumatic
- Sub-acute and dehisced wounds
- Ulcers (such as pressure or diabetic)
- Flaps and grafts
- Partial-thickness burns

Contraindications

The use of the RENASYS system is contraindicated in the presence of:
- Necrotic tissue with eschar
- Untreated osteomyelitis
- Malignancy in wound (with exception of palliative care to enhance quality of life)
- Exposed arteries, veins, organs or nerves
- Non-enteric, unexplored fistulas
- Anastomotic sites
RENASYS® EZ Plus/RENASYS GO

Warnings

Note: Full device operation instructions are found in the User Guide for each RENASYS device

1. Patients must be monitored closely for bleeding. If sudden or increased bleeding is observed, immediately discontinue therapy, take appropriate measures to stop bleeding and contact the treating clinician.

2. Patients suffering from difficult hemostasis or who are receiving anticoagulant therapy have an increased risk for bleeding. During therapy, avoid using hemostatic products that, if disrupted, may increase the risk of bleeding.

3. Sharp edges or bone fragments in a wound must be covered or removed prior to using the RENASYS system due to risk of puncturing organs or blood vessels while under negative pressure.

4. Do not use the RENASYS device directly on exposed blood vessels, organs or nerves.

5. In the event defibrillation is required, disconnect the device from the wound dressing prior to defibrillation. Remove the wound dressing if the location will interfere with defibrillation.

6. The RENASYS device is not MRI or CT compatible. Disconnect the pump from the patient and do not bring the device into the MRI suite or scanner range.

7. When operating, transporting, repairing or disposing of RENASYS device and its accessories, the risk of infectious liquids being aspirated or contamination of the device cannot be eliminated. Universal precautions should be observed whenever working with potentially contaminated parts or equipment.

8. RENASYS devices have not been studied on pediatric patients. Patient size and weight should be considered when prescribing this device.

9. RENASYS devices are not suitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).

   Special precautions for Hyperbaric Oxygen Chambers (HBO): oil-emulsion and Petrolatum based dressings are not recommended for use on patients undergoing HBO therapy and should be removed prior to therapy and/or a consideration of use under the NPWT dressing on patients undergoing HBO therapy.

10. The RENASYS devices (pumps) and the RENASYS canister kits are provided non-sterile and should not be used in a sterile field.
Precautions

Note: Full device operation instructions are found in the User Guide for each RENASYS device

1. Precautions should be taken for patients who are or maybe:
   • Receiving anticoagulant therapy or platelet aggregation inhibitors, actively bleeding or have weakened blood vessels or organs.
   • Suffering from difficult wound hemostasis.
   • Untreated for malnutrition.
   • Noncompliant or combative.
   • Suffering from wounds in close proximity to blood vessels or delicate fascia.

2. Infected wounds may require more frequent dressing changes. Regular monitoring of the wound must be maintained to check for signs of infection.

3. Therapy should remain ON for the duration of the treatment. There may be situations when the patient needs to be disconnected from the NPWT device, for example, for activities of daily living and diagnostic testing. If the patient needs to be disconnected, the suction tubing should be disconnected and the ends of the tubing capped. How long patients may be disconnected from the NPWT device is a clinical decision based on individual characteristics of the patient and the wound. Factors to be considered would include amount of drainage, location of the wound, integrity of the dressing seal, assessment of bacterial burden in the wound and patient's risk of infection. The RENASYS devices have an Intermittent Mode with a 5 minute ON/2 minute OFF cycle appropriate for wound care usage as prescribed by the treating clinician.

5. This device should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which the RENASYS system is being used.

6. If the device has been at temperatures below freezing, bring the device to room temperature prior to use or the unit may be damaged.

7. Ensure that tubing is installed completely, connected correctly and without any kinks to avoid leaks or blockages in the vacuum circuit.

8. Position the device and tubing appropriately to avoid the risk of causing a trip hazard and of the patient lying on the tubing. Where possible, the device system tubing should be positioned horizontal with or below the wound.

9. When bathing/showering, the patient must be disconnected from the device.

10. If any liquids penetrate the device, discontinue use and return to your authorized provider for service.

11. Do not apply NO-STING SKIN-PREP™ directly onto open wounds.

12. Maintain regular monitoring of the RENASYS device and the wound site during therapy to ensure therapeutic treatment and patient comfort. The vacuum level should never be painful. If the patient reports discomfort with the vacuum level, consider reducing the pressure.

13. Underlying structures, such as bone and tendon, must be covered by the non-adherent dressing layer.

14. A RENASYS device is only to be used with Smith & Nephew authorized components.

15. Ensure the dressing clamp is engaged prior to switching off the device. For reconnection to the device, ensure that the device is active prior to opening the dressing clamp.
Additional device (pump) specific precautions:

RENASYS® GO carry bag contains magnets which may influence the function of certain electrical devices, including pacemakers.

RENASYS EZ Plus:
1. Contains an in-line overflow protection/bacteria guard. Inspect the Bacterial Overflow Guard on the canister and replace the canister as necessary. At minimum, the canister should be changed weekly.
2. Should only be used with Smith & Nephew 250mL S- (Sealed) and 800mL S-Canister Kits.
3. The device should only be used in the upright position.
2. General therapy considerations

Wound assessment

Success of the NPWT treatment depends heavily upon the quality of the clinical wound assessment. The wound should have a detailed assessment at the initiation of the NPWT treatment regime and with every dressing change thereafter. The following areas should be addressed with every wound assessment:

Wound size: length, width, depth
• NPWT has the ability to assist with removal of interstitial fluid and sloughy necrosis. With the removal of the space filling materials, the volume of the wound may increase slightly. This will likely happen within the first few dressing changes, especially if the wound is in the inflammatory phase of wound healing.

Granulation tissue: amount and description
• Healthy granulation tissue should be beefy red and not bleed easily. No trauma should occur to the granulation tissue with dressing removal. A Non-Adherent dressing or a contact layer may be used.

Epithelialization: amount and description
• Epithelialization should be “silvery” in appearance. The new cells are very fragile. If undermining is present, it is important to fill the undermined areas with gauze or foam to prevent the edges from rolling under.

Necrotic tissue: type and amount
• NPWT, along with the autolytic environment established by the Transparent Film, may result in a decrease in necrotic slough.
• Presence of eschar is a contraindication. Eschar should be debrided before NPWT is initiated.

Exudate: type, amount and consistency
• Assess wound exudate for type, amount, color and consistency. Evaluate the wound exudate for consistent characteristics with the wound type and the anticipated exudate. Significant changes in exudate warrant a re-assessment of the wound.

Odor: present/absent, description
• It is important to note that body fluids that have been contained in a sealed system for an extended period of time will likely have an unpleasant odor. This odor is not a direct indication of wound infection. Remove the soiled dressing from the wound and discard per facility protocol. Clean wound per protocol, and then, if an odor persists, an assessment for presence of an infection may be necessary.

Pain: use facility approved tool for rating pain
• There should not be pain with the RENASYS™-G Gauze Dressing Kit. If the patient experiences pain, decrease the amount of pressure. The pressure range is 40-120mmHg which should allow for pressure adjustment to ensure pain-free NPWT therapy.
• When using the RENASYS-F Foam Dressing Kit, tissue adherence may be reduced by use of a contact layer, decreasing the pressure, and/or increasing the frequency of the dressing changes.
Choosing a NPWT wound filler/wound interface

Factors to consider include:

- Wound size and volume
- Contour of wound bed
- Amount and type of exudate
- Patient comfort and preference
- Characteristics of granulation tissue
- Caregiver skills

Wound size considerations:

- Small to moderate size wounds with shallow to deep depth: both foam and gauze may be used with similar ease of application
- Moderate to large surface area wounds with shallow depth: gauze is generally considered easier to apply
- Moderate to large surface area wounds with deep depth: foam may be considered easier to use

Wound bed contour considerations:

- Distribution of pressure requires intimate contact with entire wound surface.
  - Smooth wound bed contour
  - Irregular contour – undermining or tunneling
- Ease of application.
  - Surface area
  - Wound depth
  - Anatomical location

Wound bed with irregular contour

Wound bed contour

Gauze wound filler easily maintains contact with irregular surface

Foam wound filler may not intimately contact irregular shape spaces in wound bed
The choice of wound filler will be influenced by the amount and consistency of wound exudate

Note: In wounds with large amounts of exudate a wound interface (non-adherent layer) is generally not recommended.

If using gauze with larger amounts of exudate, the drain should be placed close to the wound bed over a single layer of gauze.

Patient comfort

- The RENASYS™-G Gauze Dressing Kit should be changed 48 hours after initiating therapy to assess the patient’s response to the therapy. If the patient is comfortable and the wound is responding positively to the therapy, the subsequent dressing change frequency is 2-3 times per week.
- Pain is a very subjective experience and will vary with each patient. Research has validated that patients report less pain with gauze.

Granulation tissue

- NPWT with foam wound filler has historically been used to prepare wounds for grafting. More recently gauze has been used by plastic surgeons and feedback suggests that the granulation tissue is smoother, less inflamed and an excellent bed for receiving a STSG.

Skin grafts

- NPWT with gauze has been found to give excellent results on irregular and mobile surfaces.
Gauze/foam combination therapy:

RENASYS™-G Gauze Dressing and RENASYS-F Foam Dressing can be used in combination in a wound being treated with negative pressure wound therapy. While combination therapy may be of benefit for optimizing the best wound healing environment for the patient, this option is dependent on the individual wound characteristics and clinical judgment.

It is appropriate to use a combination foam/gauze therapy where the HCP determines the necessity for this combination therapy. Examples may include wounds that have explored tunnels, undermining or sinus tracts with an open central area. The moistened gauze can be placed in these areas with foam placed on top ensuring the foam is in contact with the gauze. Another type of wound that may be appropriate for combination therapy is a circumferential wound where the gauze is wrapped around an extremity in combination with the foam placed in areas to assist in managing removal of exudate.

NPWT and combination therapy for infected wounds:

If the wound is infected, consider using one of the Smith & Nephew’s ACTICOAT® products to address the infection. ACTICOAT Flex 3 and ACTICOAT Flex 7 are both compatible with either RENASYS systems or PICO Single Use Negative Pressure Wound Therapy System. ACTICOAT 3 or ACTICOAT 7 may also be used with the RENASYS systems if the dressings are fenestrated for application.
Considerations for pump selection

Both the RENASYS® EZ Plus and RENASYS Go devices can be used on a variety of wounds.

Optimally the RENASYS EZ Plus is recommended for:
- Moderate to large volume wounds
- Difficult to seal locations
- High exudate levels
- Large surface area wounds
- Open abdominal wounds
- Acute setting/hospitalized, limited ambulatory patients

Optimally the RENASYS GO is recommended for:
- Small to medium volume wounds
- Low to moderate exudate levels
- Home care setting
- Ambulatory patients
RENASYS® portfolio – pumps and canisters

These NPWT Clinical Guidelines are for use with the RENASYS and PICO® systems. The systems do not have the same features or require the same guidelines. Refer to specific quick reference guides, Instructions for Use (IFU) or specific product user manuals for additional instructions. There may be certain unique indications, contraindications, precautions and warnings for each individual product.

RENASYS EZ Plus
Component list
- Pump
- Canister holder kit
- Power cord
- Quick reference guide

RENASYS GO
Component list
- Pump
- Power cord
- Quick reference guide
- Strap

800mL S-Canister
Component list; 10 kits per case
- Sealed canister
- With or without solidifier
- Overflow guard with silicone tubing
- Canister tubing

250mL S-Canister
Component list; 10 kits per case
- Sealed canister
- Solidifier
- Overflow guard with silicone tubing
- Canister tubing

RENASYS GO Large Canister (750mL)
Component list; 5 per case
- Sealed canister
- Solidifier
- Canister tubing

RENASYS GO Canister (300mL)
Component list; 5 per case
- Sealed canister
- Solidifier
- Overflow guard with silicone tubing
- Canister tubing
Dressing change frequency

The RENASYS™-G Gauze and/or RENASYS-F Foam Dressing Kits should be changed 48 hours after initiating therapy to assess the patient’s response to the therapy. If the patient is comfortable and the wound is responding positively to the therapy, the subsequent dressing change frequency is 2-3 times per week or 48 to 72 hours.

Check dressings at regular intervals. Infected wounds may require more frequent dressing changes. Monitor the wound to assess for changes in signs or symptoms of infection.

Throughout treatment, monitor for any signs of local or systemic infection. If there are any signs of systemic infection or advancing infection at the wound site, contact the treating physician/clinician immediately.

Tips and tricks for improving dressing wear time

To enhance dressing wear time, use these basic wound care tips:

• SKIN-PREP™ should be routinely used to protect the periwound area. 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-PREP barrier to edges of Transparent Film to prevent rolling.

• Apply Ostomy Strip Paste and/or the RENASYS Adhesive Gel Patch to skin irregularities such as abdominal skin folds or cleft at sacrococcygeal juncture. This will help to decrease depth of the skin irregularity.

• Border Transparent Film with Waterproof Tape.

NPWT pressure settings

General guidelines:

• Recommended pressure range for the RENASYS NPWT systems is 40mmHg to 120mmHg.

• Generally a pressure level of 80mmHg is used with gauze and 120mmHg with foam. If a patient experiences discomfort, it may help to reduce the pressure level. A lower pressure range between 40mmHg-80mmHg provides less painful NPWT while handling most exudate levels, types, and consistencies.

• 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.
### Recommended pressure settings

<table>
<thead>
<tr>
<th>Wound type</th>
<th>Suggested filler</th>
<th>Pressure setting</th>
<th>Wound contact layer</th>
<th>Special considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute/traumatic</td>
<td>Gauze or foam</td>
<td>-80 to -120mmHg</td>
<td>If tendon, bone, and/or other fragile structures are exposed</td>
<td>Infected wounds and fragile structures should be protected and care taken to avoid desiccation of tendon if exposed</td>
</tr>
<tr>
<td>Partial thickness abdominal (muscle intact)</td>
<td>Foam</td>
<td>-80 to -120mmHg</td>
<td>Not required unless adhesion occurs</td>
<td>Layer the filler into the wound to ensure it fits the cavity from the bottom up to ensure contact with the wound margins</td>
</tr>
<tr>
<td>Full thickness abdominal (muscle intact)</td>
<td>Decompression &amp; closure</td>
<td>-60 to -120mmHg</td>
<td>OPL large enough to cover all fragile structures should be used</td>
<td>The lead clinician must take full responsibility for treatment choices and materials/method of NPWT and pressure setting used</td>
</tr>
<tr>
<td>Full thickness abdominal (muscle intact)</td>
<td>Abdominal dressing with OPL</td>
<td>-60 to -120mmHg</td>
<td>Essential to protect exposed fragile structures</td>
<td>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</td>
</tr>
<tr>
<td>Healing by secondary intention</td>
<td>Gauze</td>
<td>-60 to -120mmHg</td>
<td>Yes if tendon/bone exposed</td>
<td>Always address underlying etiology and factors affecting healing – if slough or necrosis present debride prior to commencement of NPWT or consider using foam</td>
</tr>
<tr>
<td>Pressure ulcers</td>
<td>Gauze</td>
<td>-60 to -80mmHg</td>
<td>Yes if tendon/bone exposed</td>
<td>Dressing should be placed as soon after surgery as is practical once hemostasis is achieved</td>
</tr>
<tr>
<td>Diabetic foot ulcers post surgery</td>
<td>Gauze</td>
<td>-60 to -80mmHg</td>
<td>Yes if tendon/bone exposed</td>
<td>Sharp debridement of any devitalized tissue should occur prior to placement of NPWT</td>
</tr>
<tr>
<td>Diabetic foot ulcers</td>
<td>Gauze or foam</td>
<td>-60 to -80mmHg</td>
<td>Yes if tendon/bone exposed</td>
<td>Dressings are typically removed after 5 days or as per clinician instructions</td>
</tr>
<tr>
<td>Meshed grafts/bioengineered tissue</td>
<td>Gauze</td>
<td>-50 to -80mmHg</td>
<td>Yes to avoid adherence of filler to the graft</td>
<td>Dressings are typically removed after 5 days or as per clinician instructions</td>
</tr>
<tr>
<td>Flaps</td>
<td>Gauze</td>
<td>-50 to -80mmHg</td>
<td>Yes to avoid adherence of filler to the graft</td>
<td>Dressings are typically removed after 5 days or as per clinician instructions</td>
</tr>
<tr>
<td>Dehisced surgical wounds</td>
<td>Foam</td>
<td>-80 to -120mmHg</td>
<td>Yes if tendon, bone, and/or other fragile structures are exposed</td>
<td>Consideration should be taken to debride any devitalized tissue prior to commencement of NPWT</td>
</tr>
<tr>
<td>Chronic wounds</td>
<td>Gauze</td>
<td>-80mmHg</td>
<td>Yes if tendon/bone exposed</td>
<td>Always address underlying etiology and factors affecting healing</td>
</tr>
<tr>
<td>Enteric fistula (explored)</td>
<td>Gauze or foam</td>
<td>-80mmHg</td>
<td>Yes to protect exposed fragile structures</td>
<td>See RENASYS® High Output Dressing Kit application technique, page 32</td>
</tr>
</tbody>
</table>
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 haemostasis 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.
Physician orders

Prior to placement of the RENASYS® device, the medical 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 Rx orders should include:

- Wound location, size, and type
- Smith & Nephew wound dressing kit type
- Vacuum settings (recommended (-40mmHg to -120mmHg)
- Frequency of dressing changes
- Adjunctive dressings

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

While the RENASYS GO therapy device is 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. If the device is set to CONTINUOUS mode (recommended) 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.

While RENASYS EZ Plus is turned on you will hear the device running and the set pressure will show on the gauge.

It is important to monitor the activity of the device while you are using the therapy.

Does the dressing have a raisin-like appearance?

Gauze with drain  Gauze with Soft Port  Foam with Soft Port
Kit sizes and components

The RENASYS-G Gauze Dressing Kit is part of the Smith & Nephew RENASYS NPWT system. The RENASYS-G Gauze Dressing Kit contains everything you need to perform the dressing change with the exception of gloves and scissors. The RENASYS-G Gauze Dressing Kit is designed to provide the clinician with many options to address most wound types, locations, and exudate levels. The table below will help guide you to the appropriate Kit size for your patients’ wounds.

<table>
<thead>
<tr>
<th>Kit Contents</th>
<th>Small</th>
<th>Medium</th>
<th>Large</th>
<th>X-Large</th>
<th>Sterile with Soft Port</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saline 30ml Bullet</td>
<td>1 bullet, 30mL</td>
<td>1 bullet, 30mL</td>
<td>1 bullet, 30mL</td>
<td>2 bullets, 30mL</td>
<td>–</td>
</tr>
<tr>
<td>Wound Ruler</td>
<td>1 wound ruler</td>
<td>1 wound ruler</td>
<td>1 wound ruler</td>
<td>1 wound ruler</td>
<td>–</td>
</tr>
<tr>
<td>NO-STING SKIN-PREP™</td>
<td>1 sachet</td>
<td>1 sachet</td>
<td>1 sachet</td>
<td>2 sachets</td>
<td>–</td>
</tr>
<tr>
<td>Soft Port</td>
<td>1 – Length 27&quot; (69cm)</td>
<td>1 – Length 27&quot; (69cm)</td>
<td>1 – Length 27&quot; (69cm)</td>
<td>1 – Length 27&quot; (69cm)</td>
<td>1 – Length 27&quot; (69cm)</td>
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<tr>
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<td>Applicator head</td>
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<td>6in x 4in (15cm x 10cm)</td>
<td>6in x 4in (15cm x 10cm)</td>
<td>6in x 4in (15cm x 10cm)</td>
<td>6in x 4in (15cm x 10cm)</td>
<td>6in x 4in (15cm x 10cm)</td>
</tr>
<tr>
<td>AMD Gauze Dressing</td>
<td>1 dressing – 6in x 6.7in (15cm x 17cm)</td>
<td>2 dressings – 6in x 6.7in (15cm x 17cm)</td>
<td>1 roll – 4.5in x 4.1yd (11cm x 4m)</td>
<td>2 rolls – 4.5in x 4.1yd (11cm x 4m)</td>
<td>1 dressing – 6in x 6.7in (15cm x 17cm)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>1 roll – 4.5in x 4.1yd (11cm x 4m)</td>
</tr>
<tr>
<td>Transparent Film</td>
<td>1 – 8in x 12in (20cm x 30cm)</td>
<td>1 – 8in x 12in (20cm x 30cm)</td>
<td>2 – 8in x 12in (20cm x 30cm)</td>
<td>3 – 8in x 12in (20cm x 30cm)</td>
<td>3 – 8in x 12in (20cm x 30cm)</td>
</tr>
<tr>
<td>Non-Adherent Gauze</td>
<td>1 – 3in x 8in (8cm x 30cm)</td>
<td>1 – 3in x 8in (8cm x 30cm)</td>
<td>2 – 3in x 8in (8cm x 30cm)</td>
<td>4 – 3in x 8in (8cm x 30cm)</td>
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</tr>
</tbody>
</table>
Antimicrobial Gauze (included in RENASYS°-G Gauze Dressing Kits and separately in RENASYS Accessory Kits)

- The primary purpose of the gauze is to fill the wound space.
- When contracted under suction it serves two functions:
  - it equally distributes negative pressure across the wound bed
  - provides a pathway or conduit for wound fluid to exit the wound
- The gauze is impregnated with 0.2% polyhexamethylene biguanide or PHMB. This antimicrobial agent is present to inhibit the proliferation of bacteria in the dressing.
- It is important to always moisten the gauze prior to placement in the wound bed.
- Moistening the gauze also ensures that the entire wound surface is in contact with the gauze.
- The Antimicrobial Gauze has been studied to sustain its antimicrobial effectiveness for 72 hours.
- If wound is exposed to fecal matter, urine, or other undesirable elements, it is suggested that the dressing be removed, wound cleaned per protocol, and a new dressing applied.
- The 72 hour efficacy of the Antimicrobial Gauze does not dictate the dressing change frequency. The frequency of the dressing change should be determined by a thorough assessment of the wound including exudate levels.
- If the system is applied correctly and the seal is maintained, the gauze will not dry out due to the occlusive nature of the sealed dressing system.

Note: The Antimicrobial Gauze is not indicated to be moistened with any solution except saline, tap water, or sterile water.
Non-Adherent Gauze

- A Non-Adherent Gauze on the wound bed maybe used to reduce the risk of pain and bleeding during dressing changes.
- This gauze is an oil-emulsion dressing that protects fragile tissue at the time of the dressing change.
- It is recommended that a Non-Adherent Gauze be placed over any exposed bone, tendon, or fragile structures as well as any part of the wound bed that may need protection.
- It is recommended that a Non-Adherent layer or contact layer be placed under the foam and/or gauze interface over meshed grafts and some bioengineered tissues (as recommended by the manufacturer).
- Cut a single layer to the size and shape of the wound bed.
- Non-Adherent Gauze is meant to be used as a contact layer.
- The Non-Adherent Gauze is air and exudate permeable.

Special precautions for Hyperbaric Oxygen Chambers (HBO): Oil-emulsion and petrolatum based dressings are not recommended for use on patients undergoing HBO therapy and should be removed prior to therapy and/or a consideration of use under the NPWT dressing on patients undergoing HBO therapy. The pump should be disconnected and NPWT discontinued during HBO therapy.

Note: It is recommended not to use the Non-Adherent Gauze under ACTICOAT™ 3, ACTICOAT 7, ACTICOAT Flex 3, or ACTICOAT Flex 7 as the oil-emulsion dressing may interfere with the effectiveness of the silver and antimicrobial effectiveness of the ACTICOAT dressings.
Transparent Film

- The Transparent Film is a gas permeable membrane designed to create a seal.
- It creates a barrier to outside contaminants.
- It needs to cover the entire wound and at least 2 inches (5.1cm) of the intact periwound skin.
- It can also be used for patching if a leak situation occurs.
- Note: In highly exuding wounds, adding SKIN-PREP™ to the periwound skin will reduce the risk of maceration.
- The Transparent Film may be cut into strips for easier application.

Saline (0.9% Sodium Chloride) 30ml Bullet

A Saline bullet may be provided in the RENASYS™-G Gauze Dressing Kit and can be used to moisten the Antimicrobial Gauze prior to placing in the wound bed.

NO-STING SKIN-PREP™ Barrier Pad

- NO-STING SKIN-PREP is used to protect the patient’s skin upon dressing removal and to assist with the adherence of the Transparent Film.
- Do not apply directly on to open wound.

Tips for increasing the dressing longevity:

- SKIN-PREP™/NO-STING SKIN-PREP should routinely be used to protect the periwound area. 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-PREP barrier to edges of Transparent Film to prevent rolling.
- Apply RENASYS Adhesive Gel Patch to skin irregularities such as abdominal skin folds or cleft at sacrococcygeal juncture. This will help to reduce depth of skin irregularity.
- Border Transparent Film with Waterproof Tape.
RENASYS®-G Gauze Dressing with Soft Port application technique

Use clean or sterile/aseptic techniques protocol. Only use RENASYS Dressing Kits approved for use with the RENASYS System.

Clean and debride
Debride any devitalized or necrotic eschar tissue. Cleanse the wound and pat dry as per local protocol.

If desired, protect the periwound skin from exposure to moisture and adhesive through the use of a skin sealant.

If desired, a non-adherent wound contact layer may be applied. Trim a single layer of Non-Adherent Gauze to fit the wound dimensions and lay across the wound bed.

If the wound is infected, consider using one of Smith & Nephew’s ACTICOAT™ products to address the infection. ACTICOAT Flex 3 and ACTICOAT Flex 7 may be used in conjunction with RENASYS NPWT treatments. ACTICOAT 3 or ACTICOAT 7 may also be used if the dressings are fenestrated for application.

Dress the wound with gauze
Apply a layer of saline-moistened antimicrobial gauze to wound bed.

Continue to apply in layers until the gauze loosely fills the entire wound cavity.

Avoid over packing the wound.

If multiple pieces of gauze are used to fill the wound, count and record how many pieces are present to ensure all pieces are removed at a dressing change.
Seal the wound
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 gauze is completely covered and the wound is sealed.

Apply the Soft Port
Cut a small hole (no less than 2.0cm) in the center of the film, over the gauze. Remove any loose Transparent Film and dispose.

Remove the adhesive backing panel from the Soft Port dressing and align directly over the hole in the Transparent Film. Use gentle pressure to anchor it to the Transparent Film.

Smooth the dressing down while removing the Soft Port stabilization frame.

Secure the 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.

Connect the Soft Port tubing to the canister tubing by pushing on the Quick-Click Connectors together. An audible click indicates the connection is secure. Activate the RENASYS® device and adjust the prescribed therapy level. Finished dressings should be firm to the touch.
Kit sizes and components

The RENASYS Soft Port simplifies and enhances negative pressure wound therapy by reducing the need for bridging which saves time and materials. The Soft Port reduces the risk of pressure-related injuries and eases patient discomfort by replacing the hard tubing with a soft, cushioned channel, while maintaining the ability to operate at peak performance when compressed, twisted or kinked by a patient or surrounding object. RENASYS-F Foam Dressing Kit is sterile, rendering it perfect for use in all care settings, from OR to home care.

<table>
<thead>
<tr>
<th>Kit contents*</th>
<th>Small</th>
<th>Medium</th>
<th>Large</th>
<th>X-Large</th>
<th>Soft Port Stand-Alone Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Soft Port</strong></td>
<td>1 – Length 27in (69cm) Applicator head 6in x 4in (15cm x 10cm)</td>
<td>1 – Length 27in (69cm) Applicator head 6in x 4in (15cm x 10cm)</td>
<td>1 – Length 27in (69cm) Applicator head 6in x 4in (15cm x 10cm)</td>
<td>1 – Length 27in (69cm) Applicator head 6in x 4in (15cm x 10cm)</td>
<td>Length 27in (69cm) Applicator head 6in x 4in (15cm x 10cm)</td>
</tr>
<tr>
<td><strong>Foam block</strong></td>
<td>1 – 4in x 3in x 1in (10cm x 8cm x 3cm)</td>
<td>1 – 8in x 5in x 1in (20cm x 13cm x 3cm)</td>
<td>1 – 10in x 6in x 1in (25cm x 15cm x 3cm)</td>
<td>1 – 20in x 25in x 0.6in (50cm x 63cm x 1.5cm)</td>
<td>–</td>
</tr>
<tr>
<td><strong>Transparent Film</strong></td>
<td>1 – 8in x 12in (20cm x 30cm)</td>
<td>2 – 8in x 12in (20cm x 30cm)</td>
<td>3 – 8in x 12in (20cm x 30cm)</td>
<td>6 – 8in x 12in (20cm x 30cm)</td>
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</tbody>
</table>

*5 kits per case
Reticulated open pore hydrophobic polyurethane foam.

- Cut foam to size and shape of the wound.
- Foam should fill the wound cavity. Do not force or pack foam into any areas of the wound.
- It may be necessary to stack pieces of foam in deeper wounds.
- A contact layer may be used under the foam if adherence or pain is a concern. Example of contact layers are Non-Adherent Gauze, ACTICOAT® 3, ACTICOAT 7, ACTICOAT Flex 3, or ACTICOAT Flex 7. It is suggested to fenestrate the ACTICOAT 3 or ACTICOAT 7 on more heavily exuding wounds.
- Rub the edges of the foam after cutting to remove any loose fragments.
- Do not cut foam directly over wound bed to avoid foam fragments from falling into the wound bed.
- It is recommended to document the number of foam pieces placed in the wound to ensure all are removed at dressing change.
- Do not place foam into blind or unexplored tunnels.
- If foam dressing adheres to wound bed:
  1. Power down device.
  2. Apply normal saline into the wound dressing and let set for 15-30 minutes.
  3. Gently remove dressing.
  4. Dispose of dressing in accordance with local guidelines.
- Tissue adherence may be reduced by use of a contact layer, decreasing the pressure and/or increasing the frequency of the dressing changes.
RENASYS® Transparent Film

- Stronger, proprietary adhesion formulation developed by Smith & Nephew provides superior adhesion to skin in a wide variety of skin moisture conditions, yet is safe and gentle for regular use and removal. It has a long, proven history of superior performance to many other types of acrylic adhesives available in the market, decreasing the chance of undesired film removal from the skin.
- Thicker film minimizes the risk of undesired tearing of the film and increases the ease of handling during application.
- More breathability allows for greater skin moisture vapor permeability without negatively affecting the seal strength. May help decrease risk of periwound skin maceration.
- More extensible film contours more easily to challenging anatomical geometries. Extends more easily with the skin to reduce leakage.
- The Transparent Film is a gas permeable membrane designed to create a seal.
- With proper use, it allows appropriate moisture balance within the dressing/wound which is essential to healing.
- It creates a barrier to outside contaminants.
- It needs to cover the entire wound and at least 2 inches (5.1cm) of the intact periwound skin.
- It can also be used for patching if a leak situation occurs.
- The Transparent Film may be cut into strips for easier application.

RENASYS Transparent Film is sold separately.

RENASYS Transparent Film
Component list; 10 kits per case
10 – Transparent Films per kit
8in x 12in (20cm x 30cm)

RENASYS Transparent Film X-Large
Component list; 10 kits per case
5 – Transparent Films per kit
16in x 25in (40cm x 60cm)
RENASYS°F Foam Dressing with Soft Port application technique

Use clean or sterile/aseptic techniques protocol. Only use RENASYS Dressing Kits approved for use with the RENASYS System.

Clean and debride
Debride any devitalized or necrotic eschar tissue. Cleanse the wound and pat dry as per local protocol.

If desired, protect the periwound skin from exposure to moisture and adhesive through the use of a skin sealant.

If desired, a non-adherent wound contact layer may be applied. Trim a single layer of Non-Adherent Gauze to fit the wound dimensions and lay across the wound bed.

If the wound is infected, consider using one of Smith & Nephew’s ACTICOAT® products to address the infection. ACTICOAT Flex 3 and ACTICOAT Flex 7 may be used in conjunction with RENASYS NPWT treatments. ACTICOAT 3 or ACTICOAT 7 may also be used if the dressings are fenestrated for application.

Dress the wound with foam
Cut foam dressing to fit the size and shape of the wound. Foam should completely fill the wound.

Do not cut the foam directly over the wound bed and after cutting brush the sides to dislodge small fragments of foam.

Place the cut foam into the wound. Avoid over packing. Do not force foam into the wound or place within an unexplored tunnel. It may be necessary to stack pieces of foam in deep wounds.

*If multiple pieces of foam are used to fill the wound, count and record how many pieces are present to ensure all pieces are removed at a dressing change.*
Section 4

Seal the wound
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.

Apply the Soft Port
Cut a small hole (no less than 2.0cm) in the center of the film, over the foam. Remove any loose Transparent Film and dispose.

Remove the adhesive backing panel from the Soft Port dressing and align directly over the hole in the Transparent Film. Use gentle pressure to anchor it to the Transparent Film.

Smooth the dressing down while removing the Soft Port stabilization frame.

Secure the 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.

Connect the Soft Port tubing to the canister tubing by pushing on the Quick-Click Connectors together. An audible click indicates the connection is secure.
Activate the RENASYS® device and adjust the prescribed therapy level. Finished dressings should be firm to the touch.
5. RENASYS® High Output Dressing Kit

Kit components

The RENASYS High Output Dressing Kit from Smith & Nephew, in conjunction with the RENASYS EZ Plus pump, is an intuitive, cost-effective, and clinically proven NPWT solution for managing explored enterocutaneous fistulas and other high output type wounds.

Component list; 10 kits per case

- 2 – 30mL saline bullets
- 4 – strips waterproof tape
- 1 – strip paste
- 1 – wound ruler
- 2 – sachets of NO-STING SKIN-PREP®
- 1 – 28 Fr round aspiration/irrigation drain 3ft (92cm)
- 2 – Non-Adherent Gauze 3in x 8in (8cm x 20cm)
- 2 – AMD gauze rolls 4.5in x 4.1yd (11cm x 4m)
- 3 – RENASYS Transparent Films 8in x 12in (20cm x 30cm)

The RENASYS High Output Kit should be used with the RENASYS EZ Plus device.

NOTE: The High Output Dressing Kit is not compatible with the RENASYS GO Device.

Irrigation/Aspiration Lumen

- This is a round, perforated, 28 French, double lumen, 7 foot long drain.
- Irrigation port for irrigating the wounds or decreasing the viscosity of the exudate.
- Double lumen allows for irrigation and instilling medication per clinician discretion.
RENASYS® High Output Dressing Kit application technique

High output/thin consistency dressing procedure

- Cover wound bed, including fistula opening, with Non-Adherent Gauze or with one layer of saline moistened AMD gauze.
- Place drain in close proximity to fistula opening and in dependent/inferior position.
- Fill remaining wound deficit with additional saline moistened AMD gauze.
- Cover with Transparent Film.
- Secure drain with Waterproof Tape using Chevron Technique.
- Apply Negative Pressure at 40-120mmHg.

Dressing change frequency

- Dressing change frequency may be greater than 3 times per week.
- If output is high, e.g. 800cc per shift or greater, the dressing integrity may only last up to 24 hours.
- This improves patient comfort by reducing dressing change frequency and is also more cost effective than traditional, non-NPWT methods of addressing a fistula.

Sediment laden output considerations

- Sediment may not flow through the gauze layer.
- May require NPWT dressing and an ostomy pouch/wound management pouch device.

Sediment laden dressing procedure

- Cover entire wound bed, excluding fistula opening, with one layer of Non-Adherent Gauze OR saline moistened AMD gauze.
- Place Irrigation/Aspiration drain in close proximity to fistula opening and in dependent/inferior position.
- Fistula opening is exposed.
- Fill wound deficit with additional saline moistened AMD gauze, continue to leave fistula opening exposed.
- Cover entire wound with Transparent Film.
- Create opening in Transparent Film over fistula opening.
- An ostomy pouch may be placed over fistula opening/hole in the Transparent Film and secured.
- Apply negative pressure at 40-120mmHg.

Note: Non-enteric, unexplored fistulae are contraindicated for NPWT.
Drain position

- Always position drain inferior or “dependent” of fistula opening to assist with fluid removal.
- Place drain openings in close proximity to fistula opening to quickly remove fluid as it is produced.

Fistula precautions

- **Never** place drain into fistula opening.
- **Never** lay drain on top of fistula opening.
- Patient’s fluid levels should be closely monitored, particularly with infants, children, and geriatrics.

Fistula location and fluid description

- The higher the fistula occurs in the bowel…the thinner, more caustic and heavier the output.
- The lower the fistula occurs in the bowel…the thicker or pastier the output.

Higher output fistula considerations

- Large volumes of thin fluids.
- Must be able to pass through gauze.

**Note:** Non-enteric, unexplored fistulae are contraindicated for NPWT.
Types of fistulas

**Drain recommendation:** Irrigation/Aspiration Drain (contained in the RENASYS™ High Output Dressing Kit)

- 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.

<table>
<thead>
<tr>
<th>Name</th>
<th>From</th>
<th>To</th>
<th>Type</th>
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</thead>
<tbody>
<tr>
<td>Enterocutaneous</td>
<td>Intestine</td>
<td>Skin</td>
<td>External</td>
</tr>
<tr>
<td>Recto-vaginal</td>
<td>Rectum</td>
<td>Vagina</td>
<td>Internal</td>
</tr>
<tr>
<td>Vesicocutaneous</td>
<td>Bladder</td>
<td>Skin</td>
<td>External</td>
</tr>
</tbody>
</table>

- Fistulas may also be described by amount of output:
  - High output – 500cc or more/24 hours
  - Moderate output – 200-500cc/24 hours
  - Low output – less than 200cc/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.
- Smith & Nephew recommends the gauze based interface when addressing high output fistulas.

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

*Note: Non-enteric, unexplored fistulae are contraindicated for NPWT.*
6. RENASYS® AB Abdominal Kit with Soft Port

Kit components

RENASYS AB Abdominal Dressing Kit is designed for use with the RENASYS EZ Plus device as a complete negative pressure wound therapy for managing open abdominal wounds. The RENASYS AB Dressing Kit includes the following components:

Component list; 5 kits per case
1 – Soft Port – length 27in (69cm) 
   applicator head 6in x 4in (15cm x 10cm)
2 – foam blocks 17in x 12in x 1in (43cm x 30cm x 3cm)
6 – RENASYS Transparent Films 8in x 12in (20cm x 30cm)
1 – Organ Protection Layer 35in x 26in (89cm x 66cm)
RENASYS® AB Abdominal Kit with Soft Port

Indications

The RENASYS AB Abdominal Dressing Kit with Soft Port is intended for use in conjunction with the RENASYS EZ Plus device and canisters as a complete NPWT system for managing open abdominal wounds.

• 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.

• 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 fistulae

• For untreated osteomyelitis

• For malignancy in the wound (with the exception of palliative care to enhance quality of life)

• When vital organs and structures are not covered with the Organ Protection Layer (OPL)

• For the presence of necrotic tissue with eschar

• For use in patients with on-going or high potential for hemorrhage and/or enteric leak

Warnings

• Hemostasis must be achieved prior to dressing application. Carefully monitor patients undergoing treatment with RENASYS AB for signs of sudden or increased bleeding. If such symptoms are observed, immediately discontinue therapy, take appropriate measures to control the bleeding, and contact the treating clinician. Precautions should be taken for patients who are, or may be:
  - Receiving anticoagulant therapy or platelet aggregation inhibitors
  - Actively bleeding or have friable blood vessels or organs
  - Suffering from abnormal wound hemostasis
  - Untreated for malnutrition
  - Noncompliant or combative
  - Suffering from wounds in close proximity to blood vessels or friable fascia

• Sharp edges such as bone fragments must be covered or removed prior to initiating therapy, due to risk of puncturing organs or blood vessels drawn closer under the action of negative pressure.

• Foam must not be tightly packed or forced into any wound area. Foam must only be placed in the wound defect once the OPL has been placed.
• In the event defibrillation is required, disconnect the device from the wound dressing only if its location will interfere with defibrillation.

• RENASYS® EZ Plus is not MRI compatible. Do not bring device into MRI suite.

• When operating, transporting, repairing or disposing of RENASYS devices and accessories, the risk of infectious liquids being aspirated, or contamination of the device assembly through incorrect use, cannot be eliminated. Universal precautions should be observed whenever working with potentially contaminated parts or equipment.

• RENASYS EZ Plus and RENASYS AB have not been studied on pediatric patients. Patient size and weight should be taken into account when prescribing this device.

• RENASYS devices are unsuitable for use in areas where there is a danger of explosion (e.g. hyperbaric oxygen unit, or in the presence of a flammable anesthetic mixture with air or nitrous oxide). Disconnect the device from the dressing prior to entering an area where this equipment will be used.

• RENASYS devices and canister kits are provided non-sterile and should not be used in a sterile field.

Precautions

Note: Full device operation instructions are found in the user guide for RENASYS EZ Plus.

• While using RENASYS AB, therapy should remain on in the CONTINUOUS mode for the duration of the treatment. If the patient must be disconnected from the device, protect the tube ends by inserting the tethered caps of the Quick-Click Connector immediately before turning off the device.

• CT scans and X-ray have the potential to interfere with some electronic medical devices. When possible, move the device out of the X-ray or scanner range, check that it is functioning correctly following the procedure.

• Whenever possible, the device and system tubing should be positioned level with or below the wound.

• The length of time a patient may be disconnected from the RENASYS EZ Plus device is a clinical decision based on individual characteristics of the patient and the wound. Factors to consider include the volume of drainage, integrity of the dressing seal, assessment of bacterial burden in the wound, and patient’s risk of infection.

• As a condition of use, RENASYS AB with the RENASYS system must only be applied and operated by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which RENASYS AB in indicated.

• During therapy, maintain regular monitoring of the device and tubing, from wound site to canister, to ensure therapeutic benefit and patient comfort.

• Position the device and tubing appropriately to avoid the risks of causing a trip hazard and of the patient lying on the tubing.

• Check the Bacterial Overflow Guard on the canister and replace the canister as necessary. Minimally, a weekly canister change is recommended. Always use the smallest practical canister size, based on the patient’s size and weight to avoid risk of significant and or unintended fluid and blood loss.

• The lowest recommended therapy pressure for using RENASYS AB with the RENASYS EZ Plus device is 80mmHg.

• If any liquids penetrate the pump, discontinue use and return to your authorized provider for service.

• While using RENASYS AB, apply Universal Precautions according to your institution’s protocols, to minimize the risk of contact with any blood-borne pathogens. Measures may include use of sterile gowns and eye protection with severely contaminated wounds.
Precautions specific to RENASYS° AB

Note: Ensure aseptic technique is used during the application of all components of RENASYS AB. Ensure the abdomen and its contents are adequately visualized, controlled and protected throughout application of dressing.

- Medical intervention with RENASYS AB should only be undertaken as part of a holistic medical management strategy, with the goal of reducing the patient's intra-abdominal pressure to normal levels. Factors to consider should include the etiology of the patient's intra-abdominal hypertension (IAH) or Abdominal Compartment Syndrome (ACS), as well as other factors (including the patient's size, weight and unique clinical situation).

- Frequent, standardized measurements of the intra-abdominal pressure (IAP) and/or abdominal perfusion pressure (APP) are recommended before, during and after treatment with RENASYS AB, as a means of guiding clinical decisions concerning management of the open abdomen.

- RENASYS AB is not intended to provide primary treatment for infection in the open abdomen. RENASYS AB may, however, be used on septic open abdomens, which are being managed in accordance with institutional clinical protocols for infection abatement, as an adjunct to the standard treatment regimen, and/or to provide a barrier to bacterial penetration.

- Use of the Organ Protection Layer is necessary to protect exposed bowel from the abdominal wall. Preventing adhesions or obstructions that may otherwise form during open abdominal wound management is a critical parameter in achieving timely primary fascial closure and reducing the chance of fistula formation. The OPL must completely cover all exposed viscera, prior to application of wound filler and subsequent activation of the NPWT system.

- Use caution when utilizing RENASYS AB with patients suffering from intestinal obstruction in the small or large bowel, which may include (but is not limited to) hernias, adhesions from previous abdominal surgery or from underlying pathologies such as Crohn's Disease or Irritable Bowel Syndrome (IBS). Obstructions may often be complicated by dehydration and/or loss of electrolytes – this is especially the case if the patient has bowel exposed.

- Patients with circulatory or intestinal anastomoses (including, but not limited to arterial grafts or gastric bypass) require careful consideration while using RENASYS AB. Patients with enteric fistula have an increased risk of abdominal contamination if output is not carefully managed during the course of treatment with RENASYS AB.

- During the course of treatment, the RENASYS AB dressing and RENASYS NPWT system will remove third space fluid in the abdominal compartment. Large volumes of fluid can be collected during the course of treatment. The volume and appearance of the fluid in both the canister and tubing should be checked and recorded frequently while the patient receiving therapy. The canister should be replaced prior to reaching full-capacity. Viscous exudates increase the risk of blockage in the system, monitor closely.

- The fluid level in the canister may be used as an approximate guide when considering the necessity of fluid resuscitation. Planning for fluid replacement should be a clinical consideration in all patients undergoing therapy with RENASYS AB.

- Planning for fluid replacement should be a clinical consideration in all patients undergoing therapy with RENASYS AB.

- Protection of the periwound skin area from moisture and adhesive irritation may be accomplished through the use of a skin sealant. Because of the risk of further damage to the periwound area, foam should never overlap onto intact skin without first protecting the skin with additional Transparent Film or a hydrocolloid dressing.
Use clean or sterile/aseptic techniques protocol. Only use RENASYS Dressing Kits approved for use with the RENASYS System.

Open abdominal wound preparation

Warning: Review all RENASYS NPWT system safety information before beginning wound preparation. Ensure adequate hemostasis has been achieved prior to dressing placement.

1. Sharp edges or bone fragments must be eliminated from wound area or covered
2. Ensure any areas of necrosis are appropriately debrided
3. Irrigate abdominal wound as needed
4. Clean and dry the periwound area

Organ Protection Layer (OPL) application

Warning: Protect vital structures such as bowel and abdominal organs with the OPL at all times during therapy. Foam should never be placed in contact with exposed bowel, arteries, veins, organs or nerves. The OPL is designed to allow application directly over exposed internal organs and can be cut or folded as desired. Either side of the OPL may be placed against the viscera.

Remove 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 properly disposed of, away from the open wound.

Ensure gloves are wet before applying the OPL. Gently position the OPL 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.

Ensure complete coverage of all viscera in the abdominal compartment with the OPL prior to filling the wound defect with foam.
Pre-shaped Foam application

Size the foam to the desired proportions by tearing along the pre-scored perforations. The foam should fit directly over the OPL while maintaining contact with the wound margins. Foam may be cut if required. Do not cut the foam directly over the wound bed. Always rub the edges of any cut foam to remove loose fragments.

Do not allow foam to contact intact skin without use of an appropriate barrier such as Transparent Film or a hydrocolloid. It may be necessary to stack multiple pieces of foam depending on the wound profile. If multiple pieces of foam are required, count and record how many pieces are used to ensure all pieces are removed upon bandage changes.

Gently place the perforated foam into the wound cavity over the OPL. Ensure the foam is sized to fit loosely in the wound defect and does not go below the level of the abdominal wall.

Transparent Film application

Holding the Transparent Film, expose one side of the adhesive backing by removing a single panel and apply it to the foam.

Apply film to the foam removing adhesive panels as well as the carrier film to seal.

Cover the foam with Transparent Film. The film should extend at least 5cm beyond the wound margin to facilitate a good seal. When using multiple pieces of film ensure the edges overlap by a minimum of 7.5cm. Avoid stretching or pulling the film to minimize tension or trauma to the periwound skin.
RENASYS® Soft Port application

Cut a hole no smaller than 2cm in the center of the film. Remove any excess trimmed film and dispose of away from the wound.

Remove the adhesive panel from the Soft Port dressing and align the port opening over the hole in the Transparent Film. Use gentle pressure to anchor the Soft Port dressing to the Transparent Film.

Smooth the dressing down while removing the stabilization frame from the Soft Port dressing.

Initiation of therapy

Ensure the canister is installed correctly and connect the in-line Bacterial Overflow Guard to the device. To prevent airflow into the device ensure the guard tubing is fully inserted past the 4th ridge into the device vacuum port. Connect the Soft Port to the canister tubing by pushing the Quick-Click Connectors together.

Activate the RENASYS EZ Plus device on continuous mode. Set the pressure to 80mmHg to commence and check the dressing has a good seal.

The finished dressing should collapse and be firm to the touch. If required, adjust the pressure setting to desired level. The recommended pressure range for temporary abdominal closure is 80-120mmHg.
Bridging – managing multiple wounds

with the RENASYS®-G Gauze Dressing Kit or the RENASYS®-F Dressing Kit and the Soft Port Dressing

Bridging Technique – this 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.

- Apply non-adherent layer to both wounds to cover fragile tissue and/or as a non-adherent if using gauze as the filler.
- Protect intact skin in area under bridge and between the wounds with Transparent Film.
- Cut additional foam or gauze and place on top of Transparent Film to form the bridge.
- Maximum distance between wounds for bridging is 10 inches (25.4cm). If the distance is greater than 10 inches a Y-Connector should be considered.
- Important: Contact must be made between the bridge foam/gauze and the foam/gauze filler in the wound bed (overlap).
- Complete NPWT dressing application technique for the RENASYS-F Foam or RENASYS-G Gauze dressings – covering both the wound and bridge with Transparent Film.
- Initiate negative pressure.
Y-Connector – managing multiple wounds

Y-Connectors are available to connect multiple wounds to a single unit.
- Compatible with RENASYS®-F Foam Dressing and RENASYS-G Gauze Dressing Kits.
- Compatible with RENASYS GO and RENASYS EZ Plus devices.

Y-Connector instruction
- Connect canister tubing to selected RENASYS Canister (if applicable). RENASYS GO canister tubing is pre-assembled.
- Attach Y-Connector tubing to canister tubing via Quick Click Connector.
- After completing the wound dressings, attach each dressing tubing to the “Y” arms of the Y-Connector using the Quick Click Connectors.
- Pressure level recommendations are the same as when addressing one wound: 40-120mmHg.
- Do not cut tubings.
- Y-Connectors are sold separately.
- It is recommended to change the Y-Connector a minimum of one time per week. Or, as a rule, change the Y-Connector with the canister change. Dressing integrity must be maintained at each dressing site.
- It is not recommended to connect an infected wound (pressure ulcer) to a non-infected wound (closed incision or graft site) via the Y-Connector.
- Do not connect wounds requiring different pressure settings.

Y-Connector vs. bridging
- Y-Connect when the distance between the two wounds is greater than 10 inches or 25.4cm.
- Bridging should be possible when the distance between the two wounds is less than 10 inches or 25.4cm.

Tips for success
- When utilizing two Soft Ports with Y-Connector, blockages are not detected unless both Soft Ports are blocked.
- If both wounds must be monitored, consider a bridging technique using a single Soft Port instead of a Y-Connector.
- When treating separate wounds the clinician should regularly check the wound being treated with the drain or Soft Port to ensure the dressing is compressed.
- When utilizing Y-Connector with the Soft Port, consider utilizing RENASYS EZ Plus pump.
Undermining and/or tunneling

Undermining

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.

Ways to address undermined wounds:

- Utilizing saline moistened gauze, fill the undermined areas and any dead space of the wound.
- Once the undermined areas have been filled with moistened AMD 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.
- Cover with Transparent Film as normal.

Tunneling or sinus tracts

A tunnel or sinus tract is a narrow opening in the wound bed that extends into adjacent tissue.

Ways to address tunnels or sinus tracts

Option 1 –

- Fill tunnels or sinus tract with moistened AMD Gauze, sterile packing strips, or ACTICOAT® Flex; pulling out/back 0.5 to 1cm to allow for healing distal to proximal.
- Make sure the tunnel filler material is visible in the wound bed to assure removal upon dressing change.
- Continue with RENASYS® dressing application technique utilizing AMD Gauze or Foam assuring that all areas of the wound are in contact with the wound filler.

Option 2 –

- Use channel drain, please see drain accessory.
- Measure tunnel by inserting the channel drain to base of tunnel.
- Pull back on the drain be 0.5-1cm to prevent pressure and allow for healing at distal end of tunnel.
- The portion of the drain in the tunnel/sinus tract is left unwrapped and free of wound filler material.
- Wrap the remainder of the drain with saline moistened AMD gauze assuring that the drain hub or drain junction is in the middle of the wound and at least one layer of moistened AMD gauze is between the drain and wound bed.
- Fill any dead space or remainder of the wound with additional saline moistened AMD gauze or foam filler.
- Cover with Transparent Film as normal and follow drain accessory kit dressing application.
**Tips for success**

- It is important to note the exudate level of the wound.
- Make sure the drain chosen adequately manages the wound's exudate level.
  - The Flat drain handles minimal to heavy drainage.
  - The Channel Drain handles scant to moderate drainage, no thick drainage, no sediment.
    - The portion of the drain that goes into the tunnel does not have to be wrapped with saline moistened gauze.
    - It is not necessary to wrap the portion of the drain contained to the wound bed as long as there is at least one layer of gauze between the drain and the wound bed.
- Make sure the level of the gauze is slightly higher than skin level to ensure the dead space is filled once the suction collapses the gauze.
- Ensure all dead space is filled with saline moistened gauze and/or packing strips.
Skin grafts (Split and full-thickness)/skin substitutes

**Treatment goal**

- Bolster the graft in place to prevent sheering and ultimate loss of the graft.
- Eliminate excess moisture that could lead to the graft lifting, preventing graft take.

**Suggested pressure setting and dressing change frequency**

- Pressure setting recommendation is 40-120mmHg.
- Ultimately, the pressure setting is a decision to be determined by the physician/clinician. Generally, lower pressure setting are utilized (60-80mmHg) for skin grafts and over skin substitutes.
  
  **NOTE:** It is recommended that you follow the manufacturer’s guidelines for NPWT use over skin substitutes.

- Initial dressing change at 3-5 days post application depending on physician/clinician preferences.
- Exudate level should decrease after the first 24-48 hours.
- Duration of therapy is also a physician/clinician decision (generally 3-10 days).
- It is required that NPWT therapy remains on continuously to ensure the graft remains bolstered at all times.

**RENASYS™-F Foam Dressing with Soft Port or RENASYS-G Gauze Dressing with Soft Port**

- Cover the entire graft with a non-adherent layer, such as ACTICOAT™ Flex 3 or ACTICOAT Flex 7. ACTICOAT 3 or ACTICOAT 7 may also be used if the dressings are fenestrated for application.
- Extend the contact layer at least 1 inch (2.54cm) past the suture/staple line.
- Cut foam or gauze to the size and shape of the contact layer.
- Place cut foam or gauze on top of the contact layer.
- Cover foam or gauze with Transparent Film and apply Soft Port per dressing application technique in the instructions for use.
Circumferential extremity dressing

**Application guide to lower limb wound with RENASYS® Soft Port**

Measure the Transparent Film and trim to size if required.

Expose one side of the adhesive backing by removing panel #1.

Gently position the Transparent Film under the patient’s limb.

Wrap the Transparent Film around the limb and remove panel #2 to seal.

Smooth the Transparent Film dressing down.

Remove the top stabilization panel #3 from either the side or the central split.
Wrap the opposing Transparent Film around the limb. Remove adhesive panel #2 to seal.

Smooth the Transparent Film dressing down around the limb.

Remove the other top stabilization panel #3 from either the side or central split.

If required use additional Transparent Film to ensure the dressing edges are adequately sealed.

Apply RENASYS® Soft Port in desired location avoiding any pressure points. (See IFU for application of port)

Connect the Soft Port to the canister tubing. Activate the RENASYS device at desired pressure and commence therapy.

**Tips for success**

- A leak in this type dressing is easily identified by a tactile coolness at the site of the leak. Patch leak with Waterproof Tape or Transparent Film to secure seal.
- Dressing should be comfortable. Remove dressing if any signs of discomfort are experienced and seek alternative treatment regime.
8. RENASYS° accessories

RENASYS Adhesive Gel Patch

The RENASYS Adhesive Gel Patch is designed for use with the existing Smith & Nephew NPWT dressing kits. RENASYS Adhesive Gel Patch is a sterile, single use dressing. It 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 an adhesive hydrogel sheet. This adhesive Gel Patch can be used as a replacement to Ostomy Paste. The wear time is 72 hours.

Component list; 5 boxes per case
- 10 gel patches per box – 4in x 2.8in (10cm x 7cm)
- Double sided silicone adhesive hydrogel

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 has the ability to 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.
- The adhesive is designed to release off the skin with little or no adhesive remaining. If some adhesive remains utilize Smith & Nephew's REMOVE® or another appropriate adhesive remover.
- Use gentle pressure to apply the RENASYS Adhesive Gel Patch to the dressing or skin site.
RENASYS\textsuperscript{\textdegree} Adhesive Gel Patch application technique

Creating a seal around drain tubing or to lift drain off skin

Cut the Gel Patch into strips in a direction that allows the backing removal ends to remain accessible.

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

Remove the remaining backing and apply tubing.

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

Ensure that the Gel Patch completely surrounds the tubing to create a seal and remove the backing. Continue with normal dressing application.
Creating a seal in challenging anatomical areas
Cut the Gel Patch into strips in a direction with backing removal ends accessible.

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

Remove the backing. Apply Transparent Film over the foam or gauze interface and the Gel Patch to create a seal and finish the dressing.

Creating a seal around wound margins
Cut Gel Patch into several strips. Remove the backing on one side only and apply to skin with gentle pressure. Remove the backing.

Continue to apply Gel Strips around wound margins ensuring that the strips overlap to create a good seal. Continue with normal dressing application.
Creating a seal in challenging areas of the foot
Cut the Gel Patch into strips in a direction with backing removal ends accessible.

Remove the backing on one side only and apply to skin with gentle pressure. Remove the backing. Apply Transparent Film over the foam or gauze interface and the Gel Patch to create a seal and finish the dressing.

Creating a seal around external fixation pins
Cut Gel Patch into strips and to a length that will cover the pin circumference. Remove the backing on one side only. Apply the lead end of the Gel Strip to the base of the pin. Gently apply pressure to the backing to ensure initial adhesion to the pin. Wrap the Gel Strip around the pin while simultaneously removing the backing.

Apply Transparent Film over the foam or gauze interface and the Gel Patch. Pinch the film at the Gel Patch/pin interface to create a seal and finish the dressing.
RENASYS® Drain Accessory Kits

The RENASYS system offers a variety of drains to handle multiple wound types in all care settings. RENASYS drains provide a conduit for negative pressure and removal of exudate from the wound cavity.

RENASYS Drain Accessory Kits are offered to complement the treatment of wounds. In addition to RENASYS Soft Port, experienced clinicians who wish to enhance the treatment regime of complex wound shapes and depths, locations, and challenging exudate conditions can choose from several options.

All drains are silicone and include a radiopaque strip for visualization under X-ray. Utilized in conjunction with the Soft Port, drains may further improve the removal of exudate from wounds with the following characteristics:

- Irregular contours
- Challenging anatomical conditions
- Explored fistulae
- Significant wound depth, involving undermining, sinus tracts and tunneling.

The RENASYS-G Dressing Technique with the drains and/or Soft Port is the constant factor that keeps the dressing change simple and cost effective. The variety of drains will accommodate any wound size or exudate level and may be used in combination with the Soft Port based upon clinical judgment, wound characteristics and desired clinical outcome.

The RENASYS System allows the physician/clinician the flexibility to choose the appropriate drain for the specific wound characteristics.

RENASYS 10 Fr Round Drain Accessory Kit

- The 10 French is designed for small, shallow wounds with minimal to no drainage. The drain is perfect for addressing lightly exuding wounds.
- The drain can be curled inside the wound to increase the suction potential or used in a linear fashion if curling is not possible.
- The design makes the round drain great for accommodating wounds with undermining.
- The drain is 100% silicone and radiopaque.

**Component list; 10 kits per case**
1 – RENASYS Y-Connector
1 – 10 Fr round drain
1 – strip paste
2 – strips waterproof tape
RENASYS® 10mm Flat Drain Accessory Kit

- The 10mm Flat Drain is soft and perforated.
- Internal baffles prevent the drain from collapsing.
- The Flat Drain can be used on both deep and shallow wounds with minimal to heavy drainage.
- The drain is 100% silicone and radiopaque.

**Component list; 10 kits per case**
1 – RENASYS Y-Connector
1 – flat drain 0.4in (10mm)
1 – strip paste
2 – strips waterproof tape

RENASYS 15 Fr Channel Drain Accessory Kit

- The Channel Drain can be used for wounds with up to moderate drainage.
- It is not designed for thick or sediment laden exudate.
- Its non-hollow, non-perforated design allows for insertion directly into tunnels without being wrapped with gauze.
- A layer of gauze is recommended between the drain and the wound bed, but is not necessary within the tunnel.
- The channel drain has four channels that run the length of the drain that perform as gutters to guide exudate to the suction source.
- The drain is 100% silicone and radiopaque.
- It is important to note that the “hub” or suction source must be contained inside the wound bed.
- The “hub” is the junction between the drain and the tubing.

**Component list; 10 kits per case**
1 – RENASYS Y-Connector
1 – 5 Fr. channel drain
1 – strip paste
2 – strips waterproof tape
RENASYS® Y-Connector (included in Drain Accessory Kit and separately in Kit Accessories)

- Compatible with RENASYS-F Foam Dressing and RENASYS-G Gauze Dressing Kits with Soft Port
- Compatible with RENASYS EZ Plus and RENASYS GO canister tubing

Component list; 10 kits per case
1 – Y-Connector per kit

Ostomy Strip Paste (included in Drain Accessory Kit)

- Ostomy Strip Paste is utilized to obtain the initial dressing seal and maintain the seal throughout the duration of the dressing.
- Ostomy Strip Paste prevents the drain from coming into contact with the patient’s skin where the drain exits the wound. This decreases the risk of pressure related breakdown in this area.
- The Ostomy Paste can also be used to alleviate any skin irregularities that may make getting a seal difficult (e.g. abdominal skin folds, cleft at the sacrococcygeal region).
- The Ostomy Paste can be used to completely border a wound located in an area that is difficult to get a seal (e.g. perirectal).

Waterproof Tape (included in Drain Accessory Kit)

- Waterproof Tape has a Zinc based adhesive that ensures proper adherence while remaining friendly to the patient’s intact skin.
- Waterproof Tape is used to secure the drain to prevent accidental removal from the wound bed.
- The Chevron technique is utilized with the Waterproof Tape to secure the drain. This technique was developed by nurses to secure IV tubing.
Description

The PICO Single Use Negative Pressure Wound Therapy System consists of a pump and two sterile dressing kits. The PICO pump maintains negative pressure wound therapy at 80mmHg (nominal) +/- 20mmHg to the wound surface. Exudate is managed by the dressing through a combination of absorption and evaporation of moisture through the outer film. PICO is intended for use in wound sizes (surface area x depth) up to 400cm² which are considered to be low to moderately exuding. The kit is intended to be used for a maximum of 7 days on low exuding wounds and 6 days on moderately exuding wounds. Therapy duration of the kit may be less than indicated if clinical practice or other factors such as wound type, wound size, rate or volume of exudate, orientation of the dressing or environmental conditions, result in more frequent dressing changes.

Indications for use

PICO is 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.

Examples of appropriate wound types include:
- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.

Contraindications

The use of PICO is contraindicated in the presence of:
- Patients with malignancy in the wound bed or margins of the wound (except in palliative care to enhance quality of life).
- Previously confirmed and untreated osteomyelitis.
- Necrotic tissue with eschar present.
- Exposed arteries, veins, nerves or organs.
- Anastomotic sites.
- Emergency airway aspiration.
- Pleural, mediastinal or chest tube drainage.
- Surgical suction.
Warnings

1. Certain patients are at high risk of bleeding complications which, if uncontrolled, could potentially be fatal. Patients must be closely monitored for bleeding. If sudden or increased bleeding is observed, immediately discontinue therapy, leave dressing in place, take appropriate measures to stop bleeding and seek immediate medical assistance.

2. The use of anticoagulants does not deem a patient inappropriate for treatment with PICO® however hemostasis must be achieved before applying the dressing. Patients suffering from difficult hemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using hemostatic products that, if disrupted, may increase the risk of bleeding. Frequent assessment must be maintained and considered throughout the therapy.

3. At all times care should be taken to ensure that the pump and tubing does not:
   - Lie in a position where it could cause pressure damage to the patient.
   - Trail across the floor where it could present a trip hazard or become contaminated.
   - Present a risk of strangulation or a tourniquet to patients.
   - Rest on or pass over a source of heat.
   - Become twisted or trapped under clothing or bandages so that the negative pressure is blocked.

4. Sharp edges or bone fragments in a wound must be covered or removed prior to using PICO due to risk of puncturing organs or blood vessels while under negative pressure.

5. In the event that defibrillation is required, disconnect the pump from the dressing prior to defibrillation. Remove the dressing if it is positioned in a location that will interfere with defibrillation.

6. MRI unsafe. PICO is not MRI compatible. Do not take PICO into the MRI suite.

7. PICO has not been studied on pediatric patients. Patient size and weight should be considered when prescribing this therapy.

8. PICO is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).

Precautions

1. Precautions should be taken in the following types of patients who are at high risk of bleeding complications:
   - Receiving anticoagulant therapy or platelet aggregation inhibitors or actively bleeding.
   - Having weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to; anastomoses, infection, trauma or radiation.
   - Suffering from difficult wound hemostasis.
   - Untreated for malnutrition.
   - Noncompliant or combative.
   - Suffering from wounds in close proximity to blood vessels or delicate fascia.

2. PICO dressings should only be applied by a healthcare professional. Dressings are not to be removed or changed by the patient.

3. Where PICO is used on infected wounds, more frequent dressing changes may be required. Regular monitoring of the wound should be maintained to check for signs of infection.

4. If deemed clinically appropriate, care should be taken that the application of a circumferential dressing does not compromise circulation.
5. PICO™ does not contain audible alarms. The pump should be carried so that it is accessible and the patient/healthcare professional can check the status routinely.

6. Although PICO can be used under clothing/bedding, it is important that occlusive materials e.g. film dressings, are not applied over the pad area of the dressing as this will impair device performance.

7. Where PICO is used on patients with fragile skin, a skin protectant such as SKIN-PREP™ should be used on areas of skin where fixation strips are to be applied. Inappropriate use or repeated application of fixation strips may otherwise result in skin stripping.

8. If reddening or sensitization occurs discontinue use and contact the treating healthcare professional.

9. Do not use PICO with oil-based products such as Petrolatum as it may compromise establishing an effective seal.

10. The use of negative pressure presents a risk of tissue ingrowth into foam when this is used as a wound filler. When using foam filler with PICO, tissue ingrowth may be reduced by using a wound contact layer or by increasing the frequency of dressing changes.

11. PICO may be used in conjunction with surgical drains provided the dressing is not placed over tubing where it exits the skin. Any surgical drain should be routed under the skin away from the edge of the dressing and function independently of the PICO Single Use Negative Pressure Wound Therapy System.

12. When showering the PICO pump should be disconnected from the dressing. Ensure the end of the tubing attached to the dressing is facing down so that water does not enter the top of the tube.

13. Do not take the pump apart.

14. The dressing should not be used with any other suction pump.

15. Do not alter or cut tubing configuration or pull on the tubing.

16. Do not cut the dressing as this may lead to loss of NPWT application.

17. Always ensure that the dressing is positioned centrally over the wound. The port should be positioned uppermost on intact skin and not extend over the wound so that the risk of fluid collecting around the port and potentially blocking the negative pressure is minimized.

18. CT scans and X-ray have the potential to interfere with some electronic medical devices. Where possible, move the device out of the X-ray or scanner range. If the device has been taken into the CT scan or X-ray range, check that it is functioning correctly following the procedure.

19. This device is single use only. Use of any part of this system on more than one patient may result in cross contamination that may lead to infection.

20. High temperatures and humidity may reduce wear times of dressings.

21. During transport, there is a potential for radio frequency interference that could affect PICO performance. If the device malfunctions, replace batteries. If not corrected, contact your caregiver to replace the device. PICO is not intended for use aboard aircraft, the batteries should be removed during air travel.

22. The potential for electromagnetic interference in all environments cannot be eliminated. Use caution if PICO is near electronic equipment such as RFID (Radio Frequency Identification) readers, anti-theft equipment or metal detectors.

23. 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.
Dressing change frequency

1. Dressings should be changed in line with standard wound management guidelines, typically every 3-4 days. More frequent dressing changes may be required depending on the level of exudate, condition of the dressing, wound type/size, orientation of the dressing, environmental considerations or other patient considerations; e.g. when PICO is used on infected wounds. At the healthcare professional’s discretion a PICO dressing may be left in place for up to 7 days.

2. Inspect the dressing regularly. If the dressing appears ready for changing (see diagrams A-C), press the orange button and disconnect the dressing from the pump. The fixation strips should be stretched away from the skin and the dressing lifted at one corner and peeled back until it has been fully removed. Apply another dressing, connect to the pump and press the orange button to reinitiate the therapy.

Guidance on wound suitability for management with PICO

PICO should be used on wounds which fit comfortably within the area of the pad, observing precautions on port positioning (on intact skin and not extending over the wound).

As a guide:

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 wound surfaces. Wounds treated with the larger dressing sizes of the PICO system should generally be no more than 2cm (4/5in.) in depth.

Exudate – PICO is intended for use on wounds where the level of exudate is low (nominally 0.6g of liquid exudate/cm² of wound area/24 hours) to moderate (nominally 1.1g of liquid exudate/cm² of wound area/24 hours). 1g of exudate is approximately equal to 1ml of exudate. When used on a moderately exuding wound, the size of the wound should generally be no more than 25% of the dressing pad area.

(A) Dressing properly positioned and is acceptable to be left in place
(B) Dressing requires change – Port may block with fluid
(C) Dressing requires change – Absorbent area is full
Instructions for use

Application

1. Remove any excess hair to ensure close approximation of the dressing to the wound. If necessary, irrigate the wound with sterile saline and pat the wound dry.

2. Using a clean technique, peel off the central release handle and place the dressing centrally over the wound to reduce the chance of wound fluid coming into contact with the port. The port should be uppermost from the wound (depending on the patient’s primary position), placed on intact skin and not extend over the wound to prevent fluid pooling around the port and blocking the negative pressure. Remove the other two handles and smooth the dressing around the wound to prevent creasing. Reposition if required to ensure border is not creased.

3. Once the dressing is in place, remove the pump and the batteries from the tray. Insert the batteries. Replace the cover. Following this all three lights should flash once (refer to Appendix VI – PICO™ IFU, table 1 on page 72).

4. Join the pump to the dressing by twisting together the tubing connectors. Press the orange button to start the application of negative pressure. The green light will start to flash indicating the system is working properly.

   Depending on the size of the wound, the pump should take up to 30 seconds to establish negative pressure wound therapy.

   If after 30 seconds the system has not established negative pressure wound therapy, the amber air leak light will illuminate. To troubleshoot refer to section (ii) of Appendix VI – PICO IFU, table 1 on page 72.

5. If using SKIN-PREP™ prior to application of the fixation strips (see Precautions), wipe the area surrounding the dressing and allow skin to dry.

6. Apply the fixation strips to each of the four sides of the dressing. Remove top carrier on the strip after each one has been applied. These strips maintain the seal over the wear time of the dressing. In awkward areas, it may be useful to apply the strips to help achieve a seal prior to switching on the pump. Place each strip so that it overlaps the dressing border by approximately 1cm (2/5in.). Ensure tubing is not twisted or trapped between clothing.

   Please note that if at any time the fixation strips are removed, the dressing should also be replaced.
Use with fillers and wound contact layers

PICO® is compatible with standard gauze and foam fillers used in traditional NPWT where this is clinically appropriate – for example on a defect wound. When a filler is used, the filler and the PICO dressing should be changed 2 to 3 times a week, according to local clinical protocol and manufacturer’s instructions. Gauze should loosely fill to the surface of the wound. Avoid over packing.

PICO may be used over the top of a non-adherent layer if required, for example over a skin graft. On infected wounds or wounds at risk of infection. ACTICOAT® Flex Silver-coated Antimicrobial Dressings may be used under PICO.

General use

Showering and bathing

Light showering is permissible; however, the pump should be disconnected (see Precautions) and placed in a safe location where it will not get wet. The dressing should not be exposed to a direct spray or submerged in water. Ensure the end of the tubing attached to the dressing is facing down so that water does not enter the top of the tube.

Cleaning

Adherence to clinical directives concerning hygiene is of prime importance. The pump may be wiped clean with a damp cloth using soapy water or a weak disinfectant solution.
For clinical support regarding Smith & Nephew NPWT devices call 1-800-876-1261.

A Clinical Hotline is available to assist patients and healthcare providers with any questions related to Smith & Nephew’s NPWT System. This includes generalized questions from the dressing techniques to troubleshooting an alarm situation.

The Hotline is available 24 hours a day, 7 days a week.

Or visit www.myrenasys.com or www.possiblewithpico.com.
Appendix I

Negative Pressure Wound Therapy product portfolio

Smith & Nephew prides itself in delivering an innovative and comprehensive NPWT product portfolio that offers flexibility and clinical excellence. Our extensive selection of pumps, canisters, kits and accessories are each conformably designed to meet the unique complexities of your patients’ wounds. The RENASYS® NPWT System helps improve the overall patient experience by promoting wound healing throughout the entire continuum of care.

### RENASYS EZ Plus NPWT System

#### RENASYS EZ Plus device

<table>
<thead>
<tr>
<th>Product description</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td>RENASYS EZ Plus</td>
<td></td>
</tr>
<tr>
<td>Component list</td>
<td></td>
</tr>
<tr>
<td>• Pump</td>
<td>Smith &amp; Nephew 66800697</td>
</tr>
<tr>
<td>• Canister holder kit</td>
<td>Acute Care (UHS) ZNP</td>
</tr>
<tr>
<td>• Power cord</td>
<td>Home Care (Apria) M046689</td>
</tr>
<tr>
<td>• Quick reference guide</td>
<td></td>
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</table>

#### RENASYS EZ Plus canisters

<table>
<thead>
<tr>
<th>Component list</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td>800mL S-Canister</td>
<td></td>
</tr>
<tr>
<td>Component list; 10 kits per case</td>
<td></td>
</tr>
<tr>
<td>• Sealed canister</td>
<td>Smith &amp; Nephew 66800912</td>
</tr>
<tr>
<td>• With or without solidifier</td>
<td>Acute Care (UHS) 2012025</td>
</tr>
<tr>
<td>• Overflow guard with silicone tubing</td>
<td>Home Care (Apria) M047411</td>
</tr>
<tr>
<td>• Canister tubing</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component list</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td>250mL S-Canister</td>
<td></td>
</tr>
<tr>
<td>Component list; 10 kits per case</td>
<td></td>
</tr>
<tr>
<td>• Sealed canister</td>
<td>Smith &amp; Nephew 66801066</td>
</tr>
<tr>
<td>• Solidifier</td>
<td>Acute Care (UHS) TBD</td>
</tr>
<tr>
<td>• Overflow guard with silicone tubing</td>
<td></td>
</tr>
<tr>
<td>• Canister tubing</td>
<td></td>
</tr>
</tbody>
</table>

#### RENASYS EZ Plus accessories

<table>
<thead>
<tr>
<th>Component list</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td>RENASYS EZ Plus</td>
<td></td>
</tr>
<tr>
<td>Canister Holder Kit</td>
<td>Smith &amp; Nephew 66800560</td>
</tr>
<tr>
<td>(accommodates all canister sizes)</td>
<td>Acute Care (UHS) 2009475</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component list</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td>RENASYS EZ Power Cord</td>
<td>Smith &amp; Nephew 66800193</td>
</tr>
<tr>
<td>Hospital Grade</td>
<td>Acute Care (UHS) 2009325</td>
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### RENASYS GO NPWT System

#### RENASYS GO device

<table>
<thead>
<tr>
<th>Component list</th>
<th>Product code</th>
</tr>
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<tbody>
<tr>
<td>RENASYS GO</td>
<td>Smith &amp; Nephew 66800164</td>
</tr>
<tr>
<td>• Pump</td>
<td>Acute Care (UHS) ZNG</td>
</tr>
<tr>
<td>• Power cord</td>
<td>Home Care (Apria) M040511</td>
</tr>
<tr>
<td>• Quick reference guide</td>
<td></td>
</tr>
<tr>
<td>• Strap</td>
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#### RENASYS GO canisters

<table>
<thead>
<tr>
<th>Component list</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td>RENASYS GO Large Canister (750mL)</td>
<td></td>
</tr>
<tr>
<td>Component list; 5 per case</td>
<td></td>
</tr>
<tr>
<td>• Sealed canister</td>
<td>Smith &amp; Nephew 66800914</td>
</tr>
<tr>
<td>• Solidifier</td>
<td>Acute Care (UHS) 2012250</td>
</tr>
<tr>
<td>• Canister tubing</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Component list</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td>RENASYS GO Canister (300mL)</td>
<td></td>
</tr>
<tr>
<td>Component list; 5 per case</td>
<td></td>
</tr>
<tr>
<td>• Sealed canister</td>
<td>Smith &amp; Nephew 66801066</td>
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<tr>
<td>• Solidifier</td>
<td>Acute Care (UHS) 2009325</td>
</tr>
<tr>
<td>• Overflow guard with silicone tubing</td>
<td>Home Care (Apria) M047406</td>
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<td>• Canister tubing</td>
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#### RENASYS GO accessories

<table>
<thead>
<tr>
<th>Component list</th>
<th>Product code</th>
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<tbody>
<tr>
<td>RENASYS GO Power Supply External Cord</td>
<td></td>
</tr>
<tr>
<td>1 per case</td>
<td>Smith &amp; Nephew 66800161</td>
</tr>
<tr>
<td></td>
<td>Acute Care (UHS) 1901102</td>
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<tr>
<td></td>
<td>Home Care (Apria) R037398</td>
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</table>

<table>
<thead>
<tr>
<th>Component list</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td>RENASYS GO Carrying Case</td>
<td></td>
</tr>
<tr>
<td>1 per case</td>
<td>Smith &amp; Nephew 66800163</td>
</tr>
<tr>
<td></td>
<td>Acute Care (UHS) 2009550</td>
</tr>
<tr>
<td></td>
<td>Home Care (Apria) R037472</td>
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### RENASYS GO Single Use NPWT System

#### PICO device

<table>
<thead>
<tr>
<th>Product description</th>
<th>Product code</th>
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</thead>
<tbody>
<tr>
<td>Dressing size 4in x 8in (10cm x 20cm)</td>
<td>Smith &amp; Nephew 66800862</td>
</tr>
<tr>
<td>3 kits/case</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product description</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dressing size 4in x 12in (10cm x 30cm)</td>
<td>Smith &amp; Nephew 66800863</td>
</tr>
<tr>
<td>3 kits/case</td>
<td></td>
</tr>
</tbody>
</table>
Product description | Product code
---|---
Dressing size 6in x 6in (15cm x 15cm) | Smith & Nephew 66800865
Dressing size 6in x 8in (15cm x 20cm) | Smith & Nephew 66800866
Carry Bag 1/each | Smith & Nephew 66800918

### Gauze

#### RENASYS-G

**Gauze Dressing Kit with Soft Port – Small**
- Component list; 5 kits per case
  - 1 - saline bullet 30mL
  - 1 - wound ruler
  - 1 - sachet of NO-STING SKIN-PREP
  - 1 - Soft Port – length 27in (69cm) applicator head 6in x 4in (15cm x 10cm)
  - 2 - RENASYS Transparent Films 8in x 12in (20cm x 30cm)
  - 1 - non-adherent gauze 3in x 8in (8cm x 20cm)

**Gauze Dressing Kit with Soft Port – Medium**
- Component list; 5 kits per case
  - 1 - saline bullet 30mL
  - 1 - wound ruler
  - 1 - sachet of NO-STING SKIN-PREP
  - 1 - Soft Port – length 27in (69cm) applicator head 6in x 4in (15cm x 10cm)
  - 2 - RENASYS Transparent Films 8in x 12in (20cm x 30cm)
  - 1 - non-adherent gauze 3in x 8in (8cm x 30cm)

**Gauze Dressing Kit with Soft Port – Large**
- Component list; 5 kits per case
  - 1 - saline bullet 30mL
  - 1 - wound ruler
  - 1 - sachet of NO-STING SKIN-PREP
  - 1 - Soft Port – length 27in (69cm) applicator head 6in x 4in (15cm x 10cm)
  - 1 - AMD gauze roll 4.5in x 4.1yd (11cm x 4m)
  - 2 - RENASYS Transparent Films 8in x 12in (20cm x 30cm)
  - 2 - non-adherent gauze 3in x 8in (8cm x 30cm)

**Gauze Dressing Kit with Soft Port – X-Large**
- Component list; 5 kits per case
  - 2 - saline bullets 30mL
  - 1 - wound ruler
  - 1 - Soft Port – length 27in (69cm) applicator head 6in x 4in (15cm x 10cm)
  - 2 - RENASYS Transparent Films 8in x 12in (20cm x 30cm)
  - 1 - non-adherent gauze 3in x 8in (8cm x 20cm)
  - 2 - AMD gauze rolls 4.5in x 4.1yd (11cm x 4m)
  - 3 - RENASYS Transparent Films 8in x 12in (20cm x 30cm)

### Foam

#### RENASYS-F

**Foam Dressing Kit with Soft Port – Small**
- Component list; 5 kits per case
  - 1 - Soft Port – length 27in (69cm) applicator head 6in x 4in (15cm x 10cm)
  - 1 - foam block 4in x 3in x 1in (10cm x 8cm x 3cm)
  - 1 - RENASYS Transparent Films 8in x 12in (20cm x 30cm)

**Foam Dressing Kit with Soft Port – Medium**
- Component list; 5 kits per case
  - 1 - Soft Port – length 27in (69cm) applicator head 6in x 4in (15cm x 10cm)
  - 1 - foam block 4in x 3in x 1in (10cm x 8cm x 3cm)
  - 1 - RENASYS Transparent Films 8in x 12in (20cm x 30cm)
  - 2 - RENASYS Transparent Films 8in x 12in (20cm x 30cm)

**Foam Dressing Kit with Soft Port – Large**
- Component list; 5 kits per case
  - 1 - Soft Port – length 27in (69cm) applicator head 6in x 4in (15cm x 10cm)
  - 1 - foam block 10in x 6in x 1in (25cm x 15cm x 3cm)
  - 3 - RENASYS Transparent Films 8in x 12in (20cm x 30cm)

**Foam Dressing Kit with Soft Port – X-Large**
- Component list; 5 kits per case
  - 1 - Soft Port – length 27in (69cm) applicator head 6in x 4in (15cm x 10cm)
  - 1 - foam block 20in x 25in x 0.6in (50cm x 63cm x 1.5cm)
  - 6 - RENASYS Transparent Films 8in x 12in (20cm x 30cm)

**Abdominal Dressing Kit with Soft Port**
- Component list; 5 kits per case
  - 1 - Soft Port – length 27in (69cm) applicator head 6in x 4in (15cm x 10cm)
  - 2 - foam blocks 17in x 12in x 1in (43cm x 30cm x 3cm)
  - 6 - RENASYS Transparent Films 8in x 12in (20cm x 30cm)
  - 1 - organ protection layer 35in x 26in (89cm x 66cm)
### Kit accessories

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Product Code</th>
</tr>
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<tbody>
<tr>
<td><strong>NPWT Antimicrobial Large Gauze Roll</strong></td>
<td>Smith &amp; Nephew 66800391</td>
</tr>
<tr>
<td>Component list: 10 kits per case</td>
<td>Acute Care (UHS) 2007700</td>
</tr>
<tr>
<td>• 5 - rolls of gauze individually packaged per kit</td>
<td>Home Care (Apria) M039970</td>
</tr>
<tr>
<td><strong>RENASYS Transparent Film</strong></td>
<td>Smith &amp; Nephew 66800394</td>
</tr>
<tr>
<td>Component list: 10 kits per case</td>
<td>Acute Care (UHS) 2007775</td>
</tr>
<tr>
<td>• 10 - Transparent Films per kit</td>
<td>Home Care (Apria) M040105</td>
</tr>
<tr>
<td>8in x 12in (20cm x 30cm)</td>
<td></td>
</tr>
<tr>
<td><strong>RENASYS Transparent Film X-Large</strong></td>
<td>Smith &amp; Nephew 66800853</td>
</tr>
<tr>
<td>Component list: 10 kits per case</td>
<td>Acute Care (UHS) 2012200</td>
</tr>
<tr>
<td>• 5 - Transparent Films per kit</td>
<td>Home Care (Apria) M047412</td>
</tr>
<tr>
<td>16in x 25in (40cm x 60cm)</td>
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<tr>
<td><strong>RENASYS Y-Connector</strong></td>
<td>Smith &amp; Nephew 66800971</td>
</tr>
<tr>
<td>Component list: 10 kits per case</td>
<td>Acute Care (UHS) 2002250</td>
</tr>
<tr>
<td>• 1 - Y-Connector per kit</td>
<td>Home Care (Apria) M047412</td>
</tr>
<tr>
<td><strong>RENASYS Soft Port Stand-Alone Kit</strong></td>
<td>Smith &amp; Nephew 66800799</td>
</tr>
<tr>
<td>Component list: 5 kits per case</td>
<td>Acute Care (UHS) 2012350</td>
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<td>• 1 - Soft Port per kit</td>
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<tr>
<td>Length 27in (69cm)</td>
<td></td>
</tr>
<tr>
<td>applicator head 6in x 4in (15cm x 10cm)</td>
<td></td>
</tr>
<tr>
<td><strong>RENASYS 10 Fr Round Drain Accessory Kit</strong></td>
<td>Smith &amp; Nephew 66800972</td>
</tr>
<tr>
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<td>Acute Care (UHS) 2012375</td>
</tr>
<tr>
<td>• 1- RENASYS Y-Connector</td>
<td></td>
</tr>
<tr>
<td>• 1-10 Fr round drain</td>
<td></td>
</tr>
<tr>
<td>• 1- strip paste</td>
<td></td>
</tr>
<tr>
<td>• 2-strips waterproof tape</td>
<td></td>
</tr>
<tr>
<td><strong>RENASYS 10mm Flat Drain Accessory Kit</strong></td>
<td>Smith &amp; Nephew 66800973</td>
</tr>
<tr>
<td>Component list: 10 kits per case</td>
<td>Acute Care (UHS) 2012400</td>
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<td>• 1- RENASYS Y-Connector</td>
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</tr>
<tr>
<td>• 1- flat drain 0.4in (10mm)</td>
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<tr>
<td>• 1- strip paste</td>
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<td>• 2-strips waterproof tape</td>
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<tr>
<td><strong>RENASYS 15 Fr Channel Drain Accessory Kit</strong></td>
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<tr>
<td>Component list: 10 kits per case</td>
<td>Acute Care (UHS) 2012425</td>
</tr>
<tr>
<td>• 1- RENASYS Y-Connector</td>
<td></td>
</tr>
<tr>
<td>• 1- 15 Fr. channel drain</td>
<td></td>
</tr>
<tr>
<td>• 1- strip paste</td>
<td></td>
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<tr>
<td>• 2-strips waterproof tape</td>
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<table>
<thead>
<tr>
<th>Product Description</th>
<th>Product Code</th>
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<tbody>
<tr>
<td><strong>RENASYS Adhesive gel patch</strong></td>
<td>Smith &amp; Nephew 66801082</td>
</tr>
<tr>
<td>Component list: 5 boxes per case</td>
<td>Acute Care (UHS) TBD</td>
</tr>
<tr>
<td>• 10 gel patches per box</td>
<td>Home Care (Apria) TBD</td>
</tr>
<tr>
<td>4in x 2.8in (10cm x 7cm)</td>
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<tr>
<td>• Double sided silicon adhesive hydrogel</td>
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**RENASYS® Foam and Gauze Dressing Kits with Soft Port Negative Pressure Wound Therapy**

**INDICATIONS FOR USE**

The RENASYS®-F foam dressing kits and the RENASYS®-G gauze dressing kits with Soft Port are intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) Systems with Standard RENASYS® NPWT System to indicate for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via the removal of fluids including irritation and body fluids, wound exudates and infectious materials.

**WARNINGS**

1. Carefully monitor patients for signs of sudden or increased bleeding. If such symptoms are observed, immediately discontinue therapy, take appropriate measures to control the bleeding, and contact the treating clinician.

2. Patients suffering from difficult hemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, and using hemostatic products that, if dispersed, may increase the risk of bleeding.

3. Do not use on exposed blood vessels or organs. Sharp edges such as bone fragments must be covered or removed prior to initiating therapy, due to risk of puncturing organs or blood vessels drawn near the wound.

**PRECAUTIONS**

**NOTE:** Full device operation is found in the User Guide for each RENASYS® device.

1. Precautions should be taken for patients who may be:
   - Receiving anticoagulant therapy or platelet aggregation inhibitors.
   - Actively bleeding or have fragile blood vessels or organs.
   - Suffering from abnormal wound hemostasis.
   - Unstable for malnutrition.
   - Noncompliant or combative.
   - Suffering from wound cavity proximal to blood vessels or friable tissue.

2. CT scans of a wound may have the potential to interfere with some electronic medical devices. Where possible, move the device out of the x-ray or scan range if the device has been taken into the CT scan. Using a device with a functioning correctly and performing correctly following the procedure.

3. As a condition of use, the RENASYS® device should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which NPWT is being used.

4. If the RENASYS® device has been at temperatures below freezing, the device must be brought to room temperature prior to use or the pump unit may be damaged.

**Examples of appropriate wound types include:**

- **CHRONIC:**
  - Acute
  - Traumatic
  - Partial-thickness burns
  - Flaps and grafts

**conclusions**

- The use of NPWT is contraindicated for:
  - Intact sealed sinus tract with no signs of inflammation or infection.
  - Exposed articular, weal, veins, or nerves.
  - Malignancy in the wound with exception of palliative care to enhance quality of life.
  - Anatomically normal skin.

- Be observed whenever working with potentially contaminated parts or equipment.

- Gauze has not been studied on pediatric patients. Patient size and weight should be considered when prescribing RENASYS® devices.

- RENASYS® devices are unsuitable for use in areas where there is danger of explosion (e.g., hyperbaric oxygen unit, or in the presence of a flammable anesthetic mixture with air or nitrous oxide). Do not connect the device from the dressing prior to entering an area where this equipment will be used.

- Carafill kits are provided non-sterile and should not be placed within a sterile field.

**REFERENCES**

For patients who would benefit from a suction device (negative pressure wound therapy) with Smith & Nephew Negative Pressure Wound Therapy (NPWT) Systems with Standard RENASYS® NPWT System to indicate for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via the removal of fluids including irritation and body fluids, wound exudates and infectious materials.

**INDICATIONS FOR USE**

Negative Pressure Wound Therapy

**CLEAN AND DEBRIDE**

**DRESS WOUND WITH FOAM OR GAUZE**

- **Foam:**
  - Cut a small opening (no less than 2cm)
  - Place gentle pressure to anchor the Soft Port to the transparent film.

- **Gauze:**
  - Use gentle pressure to anchor the Soft Port to the transparent film.

- **Examples of appropriate wound types include:**
  - Chronic
  - Acute
  - Traumatic
  - Partial-thickness burns
  - Flaps and grafts

- **WARNINGS**

- **Notes:**
  - Skin sealant and wound contact layer is not included as part of RENASYS®-F or RENASYS®-G Sterile Kit.

**DRESS WOUND WITH FOAM OR GAUZE**

- **Foam and Gauze:**
  - Use gentle pressure to anchor the Soft Port to the transparent film.

- **Examples of appropriate wound types include:**
  - Chronic
  - Acute
  - Traumatic
  - Partial-thickness burns
  - Flaps and grafts

- **WARNINGS**

- **Notes:**
  - Skin sealant and wound contact layer is not included as part of RENASYS®-F or RENASYS®-G Sterile Kit.

**DRESS WOUND WITH FOAM OR GAUZE**

- **Foam:**
  - Cut a small opening (no less than 2cm)
  - Place gentle pressure to anchor the Soft Port to the transparent film.

- **Gauze:**
  - Use gentle pressure to anchor the Soft Port to the transparent film.
**PREPARATION OF OPEN-ABDOMINAL WOUND VAC/STOMA CARE**

Precautions: Before dressing the open abdominal wound, the care provider must determine the patient’s ability to care for their dressing. The patient must be able to identify the dressing, recognize the dressing changes, and maintain the dressing. The patient must also be able to identify signs of infection and recognize the patient’s need for medical attention.

1. Cleanse the wound and surrounding skin with an antiseptic solution. Allow the wound to dry.

2. Place the dressing in the wound, making sure it is secure. Be sure to follow the manufacturer’s instructions for application.

3. Secure the dressing to the skin with an elastic bandage or adhesive tape. Be sure to follow the manufacturer’s instructions for application.

**CONTRAINdications**

- The use of RENASYS AB is contraindicated when:
  - There is a risk of pneumothorax or pleural effusion.
  - There is a risk of infection or cellulitis.
  - There is a risk of tension pneumothorax.
  - There is a risk of air embolism.
  - There is a risk of hemothorax or hemothorax.
  - There is a risk of mediastinal emphysema.

**PRECAUTIONS**

- The use of RENASYS AB is contraindicated when:
  - There is a risk of pneumothorax or pleural effusion.
  - There is a risk of infection or cellulitis.
  - There is a risk of tension pneumothorax.
  - There is a risk of air embolism.
  - There is a risk of hemothorax or hemothorax.
  - There is a risk of mediastinal emphysema.

**DISADVANTAGES**

- The use of RENASYS AB is contraindicated when:
  - There is a risk of pneumothorax or pleural effusion.
  - There is a risk of infection or cellulitis.
  - There is a risk of tension pneumothorax.
  - There is a risk of air embolism.
  - There is a risk of hemothorax or hemothorax.
  - There is a risk of mediastinal emphysema.

**PRECAUTIONS**

- The use of RENASYS AB is contraindicated when:
  - There is a risk of pneumothorax or pleural effusion.
  - There is a risk of infection or cellulitis.
  - There is a risk of tension pneumothorax.
  - There is a risk of air embolism.
  - There is a risk of hemothorax or hemothorax.
  - There is a risk of mediastinal emphysema.

**DISADVANTAGES**

- The use of RENASYS AB is contraindicated when:
  - There is a risk of pneumothorax or pleural effusion.
  - There is a risk of infection or cellulitis.
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  - There is a risk of air embolism.
  - There is a risk of hemothorax or hemothorax.
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**DISADVANTAGES**

- The use of RENASYS AB is contraindicated when:
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  - There is a risk of infection or cellulitis.
  - There is a risk of tension pneumothorax.
  - There is a risk of air embolism.
  - There is a risk of hemothorax or hemothorax.
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**DISADVANTAGES**

- The use of RENASYS AB is contraindicated when:
  - There is a risk of pneumothorax or pleural effusion.
  - There is a risk of infection or cellulitis.
  - There is a risk of tension pneumothorax.
  - There is a risk of air embolism.
  - There is a risk of hemothorax or hemothorax.
  - There is a risk of mediastinal emphysema.
Appendix IV

RENASYS® High Output Dressing Kit
Negative Pressure Wound Therapy

Indications for Use
The RENASYS High Output Dressing Kit is intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) Systems to deliver negative pressure to the wound. The indications for use with the NPWT device are for the treatment of open wounds, including chronic wounds, traumatic wounds, subacute and delayed wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps, and grafts. The NPWT is appropriate for use on the following wounds:

- Chronic
- Acute
- Traumatic
- Subacute and delayed wounds
- Ulcers (such as pressure or diabetic)
- Partial-thickness burns
- Flaps and grafts

The drain in the High Output Dressing Kit is equipped with an irrigation port for irrigating the wound surface with an appropriate solution. This irrigation port is not in use, the cap should be applied to the irrigation port for irrigating the wound surface with an appropriate solution for use with the NPWT device.

Precautions Specific to the RENASYS High Output Dressing Kit Pressure Settings Recommendations
- Use device pressure settings between 40-120mmHg.
- The use of pressure settings which are higher than the recommended maximum of 120mmHg is a decision to be made by the treating physician/clinician and the individual needs of the patient should be taken into account.

Procedure
1. Cleanse wound area and pat dry per protocol. Thorough wound cleansing should occur with each dressing change.
2. Apply skin sealant to porc wound area. Do not apply No-Sting Skin Prep directly on open wound.
3. Cover wound bed, including fistula opening, with non-adherent gauze or with one layer of saline moistened gauze.
4. When the irrigation port is not in use, the cap should be applied to the port.

Dressing Changes
- PRECAUTION: Before removing the dressing, clamp the dressing tubing immediately before turning off the device.
- Step 1: Remove and dispose of dressing per institutional protocol. Thoroughly inspect the wound to ensure all gauze pieces have been removed.

NOTE: The High Output Dressing Kit is not compatible with the RENASYS GO device.

Warnings
1. Patients must be closely monitored for bleeding. If sudden or increased bleeding is observed, immediately discontinue therapy, take appropriate measures to stop bleeding and contact the treating clinician.
2. Patients suffering from difficult hemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using hemostatic products that, if disrupted, may increase the risk of bleeding.
3. Sharp edges or bone fragments in a wound must be covered or removed prior to using NPWT due to risk of puncturing organs or blood vessels while under negative pressure.
4. Do not tightly pack or force gauze into any areas of the wound.
5. Do not use NPWT on exposed blood vessels or organs.
6. In the event defibrillation is required, disconnect the NPWT device from the wound dressing prior to defibrillation. Remove the wound dressing if it will interfere with defibrillation.
7. The NPWT device is not MRI or CT compatible. Do not bring into the MRI suite or scanner range.
8. When operating, transporting, repairing or disposing of NPWT devices and accessories, the risk of infectious liquids being aspirated, or contamination of the device assembly through incorrect use, cannot be eliminated. Universal precautions should be observed when working with potentially contaminated parts or equipment.
9. NPWT has not been studied on pediatric patients. Patient size and weight should be considered when prescribing NPWT devices.
10. NPWT is unsuitable for use in areas where there is danger of explosion (e.g., hyperbaric oxygen unit).
11. Inspect the overflow protection/bacteria filter on the canister and replace the canister as necessary. At minimum, the canister should be changed weekly.
12. Underlying structures, such as tendons, ligaments and nerves should be covered with natural tissue or a non-adherent dressing layer prior to applying the NPWT dressing kit.
13. NPWT should not be painful. If the patient reports discomfort, consider reducing the pressure.
14. Always use the smallest canister volume possible – do not use the 800ml canister on patients with a high risk of bleeding.
15. Maintain regular monitoring of the NPWT device and wound site during therapy to ensure therapeutic treatment and patient comfort.
16. If any liquids penetrate the NPWT device, discontinue use and return to your authorized provider for service.
17. 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.
18. Do not use if packaging is breached or damaged.
19. Canister kits are provided non-sterile and should not be used in a sterile field.

Recommendations Based on Fistula Location and Fluid Description
- The anatomical location of the fistula in the intestine will influence the amount and type of the output.
- The higher the fistula occurs in the bowel, the thinner, more caustic and heavier the output.
- The lower the fistula occurs in the bowel, the thicker or pastier the output.

Steps
Step 1: Place transparent dressing over the wound and seal.
Step 2: Secure the 28 Fr drain with waterproof tape.
Step 3: Remove the canister tube supplied with the canister and discard. Attach the canister to the RENASYS device.
Step 4: Connect the drain directly to the canister by joining the blue connector of the drain to the canister input.

PRECAUTION: Ensure dressing tubing clamp is open and there are no kinks in the tubing.

Step 10: Activate the RENASYS device on CONTINUOUS mode beginning with 80mmHg. Check that the dressing has a good seal. Finished dressings should be firm to the touch. If required, adjust pressure setting to the desired level.

More frequent dressing changes may be needed. If there are signs of systemic infection or advancing infection at the wound site, contact the treating clinician immediately.

When bathing/showering, the patient must clamp off the dressing and disconnect from the NPWT device.

Drain position.

High Output/Thin Consistency Dressing Procedure

1. If any liquids penetrate the NPWT device, discontinue use and refer to your authorized provider for service.
2. 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.
3. Always use the smallest canister volume possible – do not use the 800ml canister on patients with a high risk of bleeding.
4. Maintain regular monitoring of the NPWT device and wound site during therapy to ensure therapeutic treatment and patient comfort.
5. If any liquids penetrate the NPWT device, discontinue use and return to your authorized provider for service.
6. 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.
7. Do not use if packaging is breached or damaged.
8. Canister kits are provided non-sterile and should not be used in a sterile field.

Modify the application of the High Output Dressing Kit as described below in accordance with the location and the fluid properties.

- When bathing/showering, the patient must clamp off the dressing and disconnect from the NPWT device.
- 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.
- Always use the smallest canister volume possible – do not use the 800ml canister on patients with a high risk of bleeding.
- Maintain regular monitoring of the NPWT device and wound site during therapy to ensure therapeutic treatment and patient comfort.
- If any liquids penetrate the NPWT device, discontinue use and return to your authorized provider for service.
- 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.
- Do not use if packaging is breached or damaged.
- Canister kits are provided non-sterile and should not be used in a sterile field.

Modify the application of the High Output Dressing Kit as described below in accordance with the location and the fluid properties.
**Appendix V**

### RENASYS® Drain Accessory Kit

**Negative Pressure Wound Therapy**

#### INDICATIONS FOR USE

The RENASYS® dressing kits and related accessories are intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) Systems. The Smith & Nephew RENASYS® NPWT Systems are indicated for patients who will benefit from a suction device (Negative Pressure Wound Therapy) as it may promote wound healing via the removal of fluids including irritation and body fluids, wound exudates and infectious materials.

#### WARNINGS AND PRECAUTIONS

For a full list of warnings and precautions, please refer to the Instructions for Use (IFU) provided with a RENASYS® Foam and Gauze Dressing Kit.

#### USING A Y-CONNECTOR

Y-connectors connect two wounds to a single device, or multiple suction adaptors to one large wound.

**Use a Y-connector for two wounds with more than 25cm between them.**

- Consider bridging the two wounds using wound filler for wounds separated by a distance larger than 25cm.
- Guidance may be found in the IFU for RENASYS® Foam and Gauze Dressing Kits.
- Y-connectors may be utilized to combine a RENASYS® Soft Port with either another Soft Port or a RENASYS® drain.
- Change Y-connectors weekly at a minimum, or with each canister change.

#### Y-CONNECTOR AND WOUND BRIDGING PRECAUTIONS

- Connecting two wounds of different etiologies (e.g., surgical dehiscence and explored fistula) via the Y-connector or a bridge is not recommended due to the risk of cross contamination.
- Connecting two wounds of differing infection status via the Y-connector or a bridge (non-infected with infected) is not recommended due to the risk of cross contamination.
- Incorporating multiple Y-connectors to a single device presents additional demands on the RENASYS® device; battery power may deplete more rapidly and/or result in additional leak alarms, depending on the extent of the demand on the unit.
- Closely monitor the dressing(s) when treating with a Y-connector. Blockages which have formed in only one of the two suction adaptors connected to the Y-connector may not be detected by the RENASYS® device. Always check dressings for compressed appearance. If dressings are not visibly compressed, and no leak alarm has sounded, a blockage is present.
- If two drains are Y-connected without a Soft Port, tightly sealed, low-exuding wounds may present a risk of nuisance blockage alarms from the RENASYS® device. If this occurs, replace one drain with a Soft Port.
- When two or more RENASYS® Soft Ports are used with a Y-connector, normal operation with RENASYS® GO should be expected. In some cases, depending on the size of those wounds and their respective seal, a leak alarm from RENASYS® GO may result. A RENASYS® EZ PLUS may be used, which will offer significantly greater tolerance for leaks. A second RENASYS® GO may also be utilized in place of a Y-connector, to handle the additional demand of all wounds.
- Therapy levels of 80 to 120mmHg are recommended when multiple wounds are connected with the Y-connector.

#### ACCESSORY DRAIN SELECTION

RENASYS® drains provide a conduit for negative pressure and removal of exudate from the wound cavity.

RENASYS® Drain Accessory kits are offered to complement the treatment of wounds in addition to RENASYS® Soft Port for experienced clinicians who wish to enhance the treatment regime of complex wound shapes and depths, locations, and challenging exudate conditions. All drains are silicone and include a radiopaque strip for visualization under x-ray. Utilized in conjunction with Soft Port, drains may further improve the removal of exudate from wounds with the following characteristics:

- Irregular contours
- Challenging anatomical conditions
- Exploded fistulae
- Significant wound depth, involving undermining, sinus tracts and tunneling

#### DRAIN APPLICATION WITH RENASYS® SOFT PORT

**CLEAN AND DEBRIDE**

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

1. Debride any devitalized or necrotic eschar tissue. Clean the wound bed and pat dry.
2. If desired, protect the periwound skin from exposure to moisture and adhesive through the use of a skin sealant.
3. If desired, a non-adherent dressing may be applied. Trim a single layer of non-adherent gauze and lay across wound bed.

**PLACED DRAIN AND DRESS WOUND WITH GAUZE**

1. Cut the drain approximately 2.5cm shorter than the base of the wound. Cut the drain if using a channel or round drain.
2. Apply a layer of saline-moistened antimicrobial gauze to the wound bed and position drain on top of gauze.
   - For Channel drain: wrap a layer of gauze around drain (Note: If placing directly into a sinus tract, no gauze is necessary on the portion of the drain in the tract)
   - Apply a strip of ostomy paste to the wound edge to secure the drain in position; place the remainder over the top of the drain and pinch in place.
3. Continue to apply gauze in layers, until the gauze loosely fills the entire wound cavity. Avoid over packing the wound.

**INITIATE THERAPY**

1. Connect both the RENASYS® Soft Port and the drain to the canister tubing by pinching the quick click connector, to the canister connector. An audible click indicates the connection to secure.
2. Activate the RENASYS® device and adjust to the prescribed therapy level. The recommended therapeutic pressure range is 80 to 120mmHg while a Y-connector is utilized during treatment.
3. Finished dressings should be firm to the touch and leak-free.

**APPLY RENASYS® SOFT PORT**

1. Insert a small opening (no less than 0.6cm) in the center of the film, over the wound filler. Remove any transparent film and dispose of away from the wound.
2. Remove the adhesive backing from the Soft Port dressing, and align the port opening directly over the hole in the transparent film. Use gentle pressure to anchor the Soft Port to the transparent film.
3. Smooth the dressing down while removing the RENASYS® Soft Port’s flaps.
4. Secure the Soft Port to the patient according to your institutional protocol.

**CONTRAINDICATIONS**

The use of NPWT is contraindicated for:

- Untreated osteomyelitis
- Exposed arteries, veins, organs or nerves
- Necrotic tissue with eschar present
- Malignancy in the wound (with exception of palliative care to enhance quality of life)
- Non-sterile and unexplored fistulas
- Anastomotic sites

**INDICATIONS FOR USE**

Negative Pressure Wound Therapy (NPWT) Systems are intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) Systems. The Smith & Nephew RENASYS® NPWT Systems are indicated for patients who will benefit from a suction device (Negative Pressure Wound Therapy) as it may promote wound healing via the removal of fluids including irritation and body fluids, wound exudates and infectious materials.
4. Warnings

1. Certain patients are at high risk of bleeding complications which, if uncontrolled, could potentially be fatal. Patients must be closely monitored for bleeding. If sudden or increased bleeding is observed, immediately discontinue therapy, leave dressing in place, take appropriate measures to stop bleeding and seek immediate medical assistance.

2. The use of anticoagulants does not deem a patient inappropriate for treatment with PICO however hemostasis must be achieved before applying the dressing. Patients suffering from difficult hemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using hemostatic products that may increase bleeding. Therapy duration of the kit may be less than indicated if clinical practice or other factors such as wound type, wound size, rate or volume of exudate, orientation of the dressing or environmental conditions, result in more frequent dressing changes.

3. Indications for use

PICO is 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.

Examples of appropriate wound types include:
- Chronic
- Acute
- Traumatic
- Subacute and dehisced wounds
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Flaps and grafts
- Closed surgical incisions

PICO Single Use Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.

3. Contraindications

The use of PICO is contraindicated in the presence of:
- Patients with malignancy in the wound bed 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.
- Anastomotic sites.
- Emergency airway aspiration.
- Pleural, mediastinal or chest tube drainage.
- Surgical suction.

5. Precautions

1. Precautions should be taken in the following types of patients who are at high risk of bleeding complications:

- Rest on or pass over a source of heat.
- Become twisted or trapped under clothing or bandages so that the negative pressure is blocked.
- Sharp edges or bone fragments in a wound must be covered or removed prior to using PICO due to risk of puncturing organs or blood vessels while under negative pressure.
- In the event that defibrillation is required, disconnect the pump from the dressing prior to defibrillation. Remove the dressing if it is positioned in a location that will interfere with defibrillation.
- MR Unsuitable. PICO is not MR compatible. Do not take PICO into the MR suite.
- PICO has not been studied on pediatric patients. Patient size and weight should be considered when prescribing this therapy.
- PICO is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).

2. Receiving anticoagulant therapy or platelet aggregation inhibitors or actively bleeding.

3. Having weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to; anastomoses, infection, trauma or radiation.

4. Suffering from difficult wound hemostasis.

5. Unremitting for malnutrition.

6. Noncompliant or combative.

7. Suffering from wounds in close proximity to blood vessels or delicate fascia.

2. Indications for use

PICO is indicated for patients who will 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.

7. Where PICO is used on patients with fragile skin, a skin protectant such as SKIN-PREP® should be used on areas of skin where fixation strips are to be applied. Inappropriate use or repeated application of fixation strips may otherwise result in skin stripping.

8. If reddening or sensitisation occurs discontinue use and contact the treating healthcare professional.

9. Do not use PICO with oil-based products such as petrolatum as it may compromise establishing an effective seal.

10. The use of negative pressure presents a risk of tissue ingrowth into foam when this is used as a wound filler. When using foam filler with PICO, tissue ingrowth may be reduced by using a wound contact layer or by increasing the frequency of dressing changes.

11. PICO may be used in conjunction with surgical drains provided the dressing is not placed over tubing where it exits the skin. Any surgical drain should be routed to anastomotic sites or exposed arteries, veins, nerves or organs.

12. When showering the PICO pump should be disconnected from the dressing. Ensure the end of the tubing attached to the dressing is facing...
13. Do not take the pump apart.
14. The dressing should not be used with any other suction pump.
15. Do not alter or cut tubing configuration or pull on the tubing.
16. Do not cut the dressing as this may lead to loss of NPWT effectiveness.
17. Always ensure that the dressing is positioned centrally over the wound. The port should be positioned uppermost on intact skin and not extend over the wound so that the risk of fluid collecting around the port and potentially blocking the negative pressure is minimized.
18. CT scans and x-ray have the potential to interfere with some electronic medical devices. Where possible, move the device out of the x-ray or scanner range. If the device has been taken into the CT scan or x-ray range, check that it is functioning correctly following the procedure.
19. This device is single use only. Use of any part of this system on more than one patient may result in cross-contamination that may lead to infection.
20. High temperatures and humidity may reduce wear times of dressings.
21. During transport, there is a potential for radio frequency interference that could affect PICO performance. If the device malfunctions, replace batteries. If not corrected, contact your caregiver to replace the device. PICO is not intended for use aboard aircraft, the batteries should be removed during air travel.
22. The potential for electromagnetic interference in all environments cannot be eliminated. Use caution if PICO is near electronic equipment such as RFID (Radio Frequency Identification) readers, anti-theft equipment or metal detectors.

6. 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 of the color of exudate.

7. Instructions for use
7.1. Guidance on wound suitability for management with PICO
PICO should be used on wounds which fit comfortably within the area of the pad, observing precautions on port positioning (on intact skin and not extending over the wound).

7.2. Application
1. Remove any excess hair to ensure close approximation of the dressing to the wound. If necessary, irrigate the wound with sterile saline and pat the wound dry.
2. Using a clean technique, peel off the central release handle and place the dressing centrally over the wound to reduce the chance of wound fluid coming into contact with the port. The port should be uppermost from the wound (depending on the patient’s primary position), placed on intact skin and not extending over the wound.

7.3. Dressing change
1. Dressings should be changed in line with standard wound management guidelines, typically every 3-4 days.
2. More frequent dressing changes may be required depending on the level of exudate, condition of the dressing, wound type/size, orientation of the dressing, environmental considerations or other patient considerations, e.g., when PICO is used on infected wounds. At the healthcare professional’s discretion a PICO dressing may be left in place for up to 7 days.
3. Inspect the dressing regularly. If the dressing appears ready for changing (see diagrams A-C), press the orange button and disconnect the dressing from the pump. The fixation strips should be stretched away from the skin and the dressing lifted at one corner and peeled back until it has been fully removed. Apply another dressing as per section 7.2, connect to the pump and press the orange button to reinitalize the therapy.

3. Based on dressing change frequency, a new PICO Single Use Negative Pressure Wound Therapy System kit will be required dependent on whichever of the following occurs first - either when both dressings have been used or after 7 days when the pump automatically stops functioning (all the lights will turn off at this point).
4. The dressing should be disposed of as clinical waste. The batteries should be removed from the pump, and both batteries and pump disposed of according to local regulations.
5. For additional information on disposal requirements see: www.possiblewithpico.com

7.4. Use with fillers and wound contact layers
PICO is compatible with standard gauze and foam fillers used in traditional NPWT where this is clinically appropriate – for example on a defect wound. When a filler is used, the filler and the PICO dressing should be changed 2 to 3 times a week, according to clinical protocol and manufacturer’s instructions. Gauze should loosely fill to the wound area/24 hours. 1g of exudate is approximately equal to 1ml of exudate. When used on a moderately exuding wound, the size of the wound should generally be no more than 25% of the dressing pad area.

As a guide:

**Depth** – Wounds greater than 0.5cm (¼ in) in depth are likely to require a foam or gauze NPWT filler to ensure adequate treatment of all the wound surfaces. Wounds treated with the larger dressing sizes of the PICO system should generally be no more than 2cm (¾ in) in depth.

**Exudate** – PICO is intended for use on wounds where the level of exudate is low (nominally 0.25g of liquid exudate/cm² of wound area/24 hours) to moderate (nominally 1g of liquid exudate/cm² of wound area/24 hours). 1g of exudate is approximately equal to 1ml of exudate. When used on a moderately exuding wound, the size of the wound should generally be no more than 25% of the dressing pad area.

7.2. Application
1. Remove any excess hair to ensure close approximation of the dressing to the wound. If necessary, irrigate the wound with sterile saline and pat the wound dry.
2. Using a clean technique, peel off the central release handle and place the dressing centrally over the wound to reduce the chance of wound fluid coming into contact with the port. The port should be uppermost from the wound (depending on the patient’s primary position), placed on intact skin and not extending over the wound.

3. Once the dressing is in place, remove the pump and the batteries from the tray. Insert the batteries. Replace the cover. Following this all three lights should flash once. (Refer to Table 1).
4. Join the pump to the dressing by twisting together the tubing connectors. Press the orange button to start the application of negative pressure. The green light will start to flash (indicates system working OK, see Table 1).

Depending on the size of the wound, the pump should take up to 30 seconds to establish negative pressure wound therapy. If after 30 seconds the system has not established negative pressure wound therapy, the amber air leak light will illuminate. To troubleshoot refer to section (iii) of Table 1.

8. General use
8.1. Showering and bathing
Light showering is permissible; however, the pump should be disconnected (see Precautions) and placed in a safe location where it will not get wet. The dressing should not be exposed to a direct spray or submerged in water. Ensure the end of the tubing attached to the dressing is facing down so that water does not enter the top of the tube.

8.2. Cleaning
Adherence to clinical directives concerning hygiene is of prime importance. The pump may be wiped clean with a damp cloth using soapy water or a weak disinfectant solution.

9. Faults and technical assistance
If your device develops a fault or there are signs of damage, refer to Table 1.
Table 1 – Pump status indication, alarms and faults

<table>
<thead>
<tr>
<th>Display status</th>
<th>Indicator status</th>
<th>Possible cause</th>
<th>Comments/trouble shooting</th>
</tr>
</thead>
<tbody>
<tr>
<td>All lights off</td>
<td>The pump is OFF</td>
<td>The therapy has been paused. Pressing the orange button will restart the therapy and the green light will flash.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>After 7 days of therapy the pump will automatically cease functioning. In this case all the lights will turn off. Pressing the orange button will not provide a green flashing light.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>If the pump has had less than 7 days usage, the batteries may not be functional and should be replaced as below:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>All lights flash once</td>
<td>This reflects the pump self test once batteries have been inserted and the cover has been replaced.</td>
<td>This is expected.</td>
</tr>
<tr>
<td>Green 'OK' light flashes</td>
<td>Dressing applied, and full system is functioning properly. No issues.</td>
<td>The pump may be heard running occasionally as it maintains the negative pressure. This is normal if this occurs frequently (several times an hour) smooth down the dressing to remove any creases that may be allowing air into the system. NPWT is still being applied in this situation.</td>
<td></td>
</tr>
</tbody>
</table>

Section (ii) – Alarms and faults

<table>
<thead>
<tr>
<th>Display status</th>
<th>Indicator status</th>
<th>Possible cause</th>
<th>Comments/trouble shooting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green 'OK' light flashes</td>
<td>System on and functioning properly</td>
<td>Battery power low.</td>
<td>Change of batteries required in &lt;24 hours. Pause the therapy by pressing the orange button.</td>
</tr>
<tr>
<td>Amber leak light flashes</td>
<td>Cessated dressing/border/strip.</td>
<td>Battery power low.</td>
<td>Change of batteries or device required in &lt;24 hours as above.</td>
</tr>
<tr>
<td>Amber battery low light flashes</td>
<td></td>
<td>Air leak detected possibly due to a</td>
<td>Smooth down the dressing and the strips to remove any creases that are allowing air into the system.</td>
</tr>
<tr>
<td>Amber leak light flashes</td>
<td></td>
<td>creased dressing/border/strip.</td>
<td>Press the orange button to restart the therapy. The green &quot;OK&quot; light will flash as the pump tries to establish therapy.</td>
</tr>
<tr>
<td>Amber battery low light flashes</td>
<td></td>
<td></td>
<td>If the air leak remains, the amber leak light will start to flash after approximately 30 seconds. If this happens, repeat smoothing actions and press the orange button.</td>
</tr>
<tr>
<td>Amber leak light flashes</td>
<td></td>
<td></td>
<td>If the leak is resolved the green light will continue to flash.</td>
</tr>
<tr>
<td>Green 'OK' light flashes</td>
<td>System is not usable.</td>
<td>Pump failed.</td>
<td>Contact S&amp;N representative.</td>
</tr>
<tr>
<td>Amber leak light flashes</td>
<td>Cessated dressing/border/strip.</td>
<td>Battery power low.</td>
<td>Apply new pump and dressing.</td>
</tr>
</tbody>
</table>

10. Specifications

<table>
<thead>
<tr>
<th>Maximum Dimensions</th>
<th>85 x 85 x 25mm (3.5 x 3.5 x 1.0&quot;)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td>&lt;120g</td>
</tr>
<tr>
<td>Operating Time</td>
<td>7 days</td>
</tr>
<tr>
<td>Battery Type</td>
<td>Lithium AA AA (L91)</td>
</tr>
<tr>
<td>Power (Battery)</td>
<td>3V DC</td>
</tr>
<tr>
<td>Ingress Protection</td>
<td>IPX4</td>
</tr>
<tr>
<td>Maximum Vacuum</td>
<td>100 mmHg</td>
</tr>
<tr>
<td>Mode of Operation</td>
<td>Continuous</td>
</tr>
<tr>
<td>Patient Protection</td>
<td>Type BF</td>
</tr>
<tr>
<td>Storage/Transport</td>
<td>5 – 25°C, 10 – 75% RH 700 to 1060 mbar atmospheric pressure</td>
</tr>
<tr>
<td>Operating Environment</td>
<td>5 – 25°C, 10 – 90% RH 700 to 1060 mbar atmospheric pressure</td>
</tr>
<tr>
<td>Compliance</td>
<td>UL 60601-1, IEC 60601-1, IEC 60601-1-2, CAN/CSA C22.2</td>
</tr>
</tbody>
</table>

11. Safety and electromagnetic compatibility

When used in accordance with the manufacturer's instructions, PICO complies with the general requirements for safety of electrical medical equipment IEC 60601-1 and the electromagnetic safety requirements of electrical medical equipment IEC 60601-1-2.

Electromagnetic compatibility

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2. These limits are designed to provide reasonable protection against electromagnetic interference typical of medical installations and home use environment. Portable and mobile RF communication equipment can affect Medical Electrical Equipment.

This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

Guidance and manufacturer's declaration – electromagnetic immunity

PICO is intended for use in the electromagnetic environment specified below. The healthcare professional or the user of PICO should assure that it is used in such an environment.

From IEC 60601, The Essential Performance for PICO is that the device should not deliver a Negative Pressure to the patient exceeding -225mmHg.
Recommended separation distances between portable and mobile RF communications equipment and PICO

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

### Immunity test

<table>
<thead>
<tr>
<th>Test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) (IEC 61000-4-2)</td>
<td>±6 kV contact ±5 kV air</td>
<td>±6 kV contact ±25 kV air</td>
</tr>
<tr>
<td>Electrical fast transient/burst (IEC 61000-4-4)</td>
<td>±2 kV for power supply lines ±1 kV for input/output lines</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Surge (IEC 61000-4-5)</td>
<td>±1 kV line(s) to line(s) ±1 kV line(s) to earth</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines (IEC 61000-4-11)</td>
<td>&lt;5% U1 or &gt;95% dip in U1 for 0.5 cycles 40% U1 or &gt;80% dip in U1 for 5 cycles 70% U1 or &gt;30% dip in U1 for 25 cycles</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Power frequency magnetic field (IEC 61000-4-8)</td>
<td>3 A/m</td>
<td>50 A/m</td>
</tr>
<tr>
<td>Conducted RF (IEC 61000-4-6)</td>
<td>3 Vrms 10kHz to 80MHz</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Radiated RF (IEC 61000-4-3)</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>30 V/m 80 MHz to 2.5 GHz</td>
</tr>
</tbody>
</table>

Note 1: At 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

\[
\text{d} = \frac{0.55 \times P_{\text{max}}}{\text{EIRP}}
\]

where P_max is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and EIRP is the effective isotropic radiated power.

WARNING: PICO should not be used adjacent to, or stacked with other electrical equipment and that if adjacent or stacked use additional measures may be necessary, such as reorienting or relocating PICO.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.

### Compliance

- **Minimum separation distance between portable and mobile RF communications equipment and PICO**:
  - 0.55 m for 100 MHz to 1,000 MHz
  - 0.175 m for 800 MHz to 2.5 GHz

### Electromagnetic environment - guidelines

- **Electromagnetic environment**:
  - Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

- **Recommended separation distance**:
  - d = 0.175P (80 MHz to 800 MHz)
  - d = 0.55P (800 MHz to 2.5 GHz)

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

### Guidance and manufacturer’s declaration – electromagnetic emissions

PICO is intended for use in the electromagnetic environment specified below. The healthcare professional or the user of PICO should assure that it is used in such an environment.

### Emissions test

<table>
<thead>
<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>PICO uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class B</td>
<td>The RF emissions characteristic of PICO make it suitable for use in hospital, transport and home-use environments.</td>
</tr>
</tbody>
</table>

### Cautions

This user guide is not intended as a guarantee or warranty. It is intended only as a guide. For medical questions please consult a physician.

The product must be used in accordance with this user guide and all applicable labelling.

PICO is packed in the UK with individual components made in the following countries:

- Smith & Nephew Medical Limited
  - 101 Hessle Road, Hull, HU3 2BH England
  - Trade Marks of Smith & Nephew
  - www.smith-nephew.com
  - Smith & Nephew Carry bag 66800918
### 13. Glossary of symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>⚡</td>
<td>Equipment Classification: Isolation Type BF applied part</td>
</tr>
<tr>
<td>🏷️</td>
<td>Single use. Do not re-use</td>
</tr>
<tr>
<td>🏭</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🌐</td>
<td>International classification</td>
</tr>
<tr>
<td>⛦️</td>
<td>Keep dry</td>
</tr>
<tr>
<td>📜</td>
<td>Lot Number</td>
</tr>
<tr>
<td>✚</td>
<td>EU: Not for general waste</td>
</tr>
<tr>
<td>🎈</td>
<td>Storage temperature</td>
</tr>
<tr>
<td>🌐</td>
<td>CE Mark</td>
</tr>
<tr>
<td>🚨</td>
<td>Attention: See instructions for use</td>
</tr>
<tr>
<td>⚠️</td>
<td>Do not use if the package is opened or damaged</td>
</tr>
<tr>
<td>☀️</td>
<td>Keep product out of sunlight</td>
</tr>
<tr>
<td>⚠️</td>
<td>Leak alert</td>
</tr>
<tr>
<td>🌋</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>🌎</td>
<td>Product is sterilised by Ethylene Oxide</td>
</tr>
<tr>
<td>✅</td>
<td>Battery power indication</td>
</tr>
<tr>
<td>✓</td>
<td>Pump is functioning properly</td>
</tr>
<tr>
<td>✞️</td>
<td>Caution: Federal (USA) law restricts this device to sale by or on order of a physician</td>
</tr>
<tr>
<td>♻️</td>
<td>Start/pause/resume therapy</td>
</tr>
</tbody>
</table>
Appendix VII
Frequently asked questions and answers

What is the suction pressure of your machine or the range of pressure that the machine achieves?
RENASYS™ GO, 40mmHg-200mmHg
RENASYS EZ Plus, 40mmHg-200mmHg
PICO™ – operates at continuous negative pressure of nominally 80mmHg

Is the pressure pre-set?
The pressure is not pre-set on the RENASYS EZ Plus or the RENASYS GO. The pressure is pre-set on the PICO system and it operates at continuous negative pressure of nominally 80mmHg.

Can it be changed?
The pressure setting on the RENASYS devices can be changed. With both pumps, the pressure can be set at different levels. The device resumes at the same level of pressure as was set when it was last turned off or put on standby.
The pressure cannot be changed on the PICO system.

Is there an Intermittent feature?
The RENASYS devices have an Intermittent feature. The PICO system does not have an Intermittent feature.

Is there a cut off which stops suction if the canister is full?
The RENASYS canisters are protected by a filter. An audible alarm will sound and a visual light flashes when the canister is full, but the devices do not turn off. The PICO system is canister-free. The larger the PICO dressing, the more fluid can be managed. Traditional NPWT may be the best option to manage wound fluid that is expected to exceed greater than 50cc in 24 hours.

Is there a one-way valve to prevent fluid from coming back through the tubing towards the patient?
The RENASYS and PICO systems have a filter that prevents fluid from coming back through the tubing toward the patient.

How long does the battery last?
RENASYS GO, 20 hours
RENASYS EZ Plus, 40 hours

The PICO system runs on two AA batteries that can be changed out if required, but should not be necessary. It is indicated for use up to 7 days, at which time the system is disposable

How much does the machine weigh? (How portable is it?)
RENASYS GO is 2.4 lbs, and comes with a shoulder strap and carry bag.
RENASYS EZ Plus is 7.4 lbs, and can be mounted on an IV pole and bed rail attachments.
PICO is less than 4.2 oz, and is small enough to easily fit in a pocket, like a smart phone.

What is the interface with the wound?
For the RENASYS systems, the wound interfaces are foam or AMD gauze. The PICO system employs a revolutionary dressing technology that manages exudate, eliminating the need for canisters.

How often do you recommend changing the dressing?
We recommend changing foam and/or AMD gauze dressings every 48-72 hours. The PICO system may be left in place for up to 7 days, depending on level of exudate.
Can you “Y” wounds together and if so how many?
Yes, we recommend Y-connecting a maximum of two wounds. PICO™ dressing cannot be Y-connected.

How do you handle undermining?
The RENASYS®-F Foam Dressing and RENASYS-G Gauze Dressing Kits with Soft Port are both indicated for undermining. We also recommend use of the RENASYS Channel Drain Kit with moistened gauze for its ability to conform to these types of wounds. The PICO system can be used to handle undermining in wounds with the addition of either a foam or gauze filler.

How do you handle fistulas?
We offer the RENASYS High Output Dressing Kit that includes a large 28Fr round irrigation aspiration drain. This kit is indicated for explored fistulas and other high output wounds.

How do you handle exposed tendon or bone?
For the RENASYS systems, we offer a Non-Adherent Gauze in our gauze kits and recommend the use of a non-adherent with a foam interface to protect exposed tendon or bone while it is under NPWT.

Do you have any special recommendations for high bioburden or infection?
We recommend the use of Smith & Nephew ACTICOAT™ Flex as a wound contact layer for wounds with a high bioburden or infection. ACTICOAT Flex is compatible for use with gauze or foam NPWT interface materials. ACTICOAT Flex is also indicated for use with PICO.
Appendix VIII

References


Additional resources


Birke-Sorensen H et al. Evidence-based recommendations for negative pressure wound therapy: Treatment variables (pressure levels, wound filler and contact layer) e Steps towards an international consensus*. Journal of Plastic, Reconstructive & Aesthetic Surgery (2011) 64, S1-S16.


With over 150 years of experience in advanced wound care, Smith & Nephew is an industry leader providing innovative solutions to meet the needs of chronic, acute and traumatic wounds across all care settings.

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