Clinical guidelines

Helping you get CLOSER TO ZERO◊ delay in wound healing

Smith+Nephew

RENASYS◊ TOUCH
Negative Pressure Wound
Therapy System

This clinical guide is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating healthcare professionals to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the products discussed in this guideline, including indications for use, contraindications, product safety information, and troubleshooting please refer to the products' label and the Instructions for Use packaged with the product.

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INTRODUCTION

Wide-ranging products

Smith & Nephew has an extensive portfolio of wound care and therapies that cover all of the major aspects of managing a wide range of wound types. The concept is well established that wounds are managed across a continuum of healing and require different therapies at each step in the continuum.

Smith & Nephew offers negative pressure wound therapy (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.[1,2]

NPWT is widely adopted as a standard treatment for patients with both acute and chronic wounds.[3] 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.[4,5]

Knowledge of when NPWT is most appropriate and when alternative therapies may be more appropriate is vitally important to maintain the efficient use of resources whilst not affecting wound outcomes negatively.[3,6,7]

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 in wound healing 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.[3]

The following clinical guidelines are intended as a reference document containing the available guidance for the treatment of wounds with RENASYS® NPWT products. The guidelines do not constitute and are not a substitute for medical advice or medical judgement. The guidelines cannot guarantee positive outcomes, wound healing or correct functioning of the RENASYS NPWT device. Not everyone who receives a product or treatment will experience the same or similar results: results may vary depending on a number of factors, including each patient's specific circumstances and condition, and compliance with the applicable instructions for use. As with any medical device, the physician/clinician is responsible for assessing the patient's individual condition and for prescribing treatment. Always consult and follow all applicable users manuals, product inserts, instructions for use, safety information and references guides for product use, operation and application.

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.[1,2] The Tissue, Infection, Moisture and Edge (epithelial margin) "T.I.M.E." scheme is a useful way of identifying and removing barriers to healing.[2] (Figure 1)

Wound bed preparation represents a combination of both scientific knowledge and practical skill; its application can help correct barriers to healing and stimulate or progress the healing process.[1] To optimise the use of Negative Pressure Wound Therapy, it is essential that clinicians ensure wound bed preparation is achieved prior to, during and after therapy.[7]

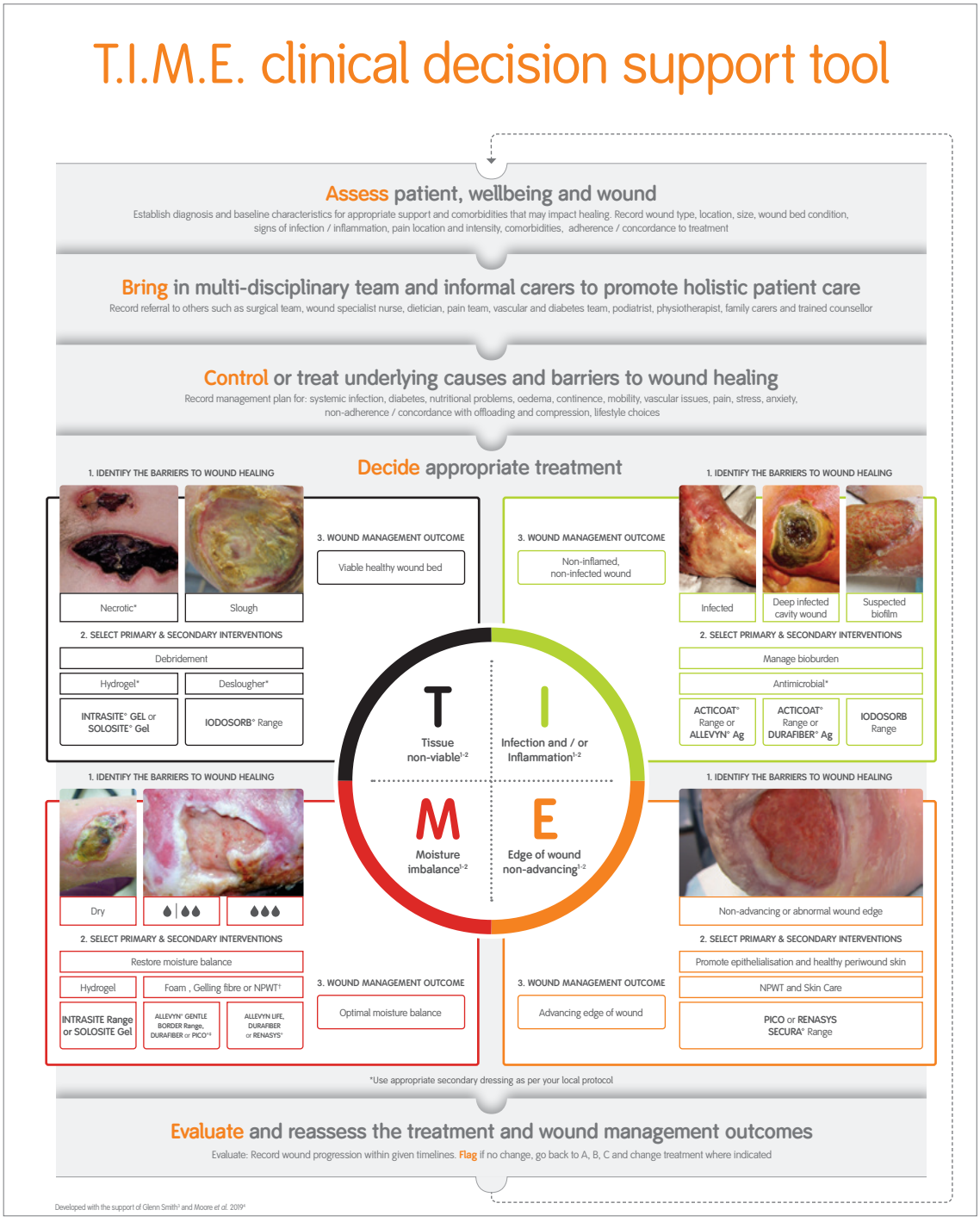


Figure 1: Categories of Smith & Nephew wound care products and their relationship to the T.I.M.E. scheme of Wound Bed Preparation

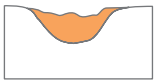
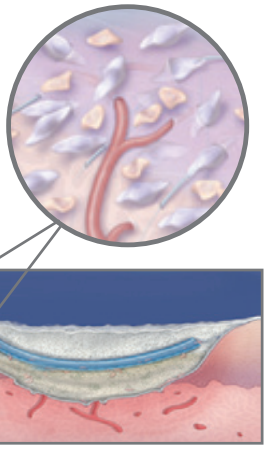
Optimisation of negative pressure wound therapy (NPWT)

Effective use of NPWT

The effective use of NPWT relies on good assessment of the patient, the wound and development of a plan for how the wound might be closed.[8]

Keys to an effective plan

Debridement, when to start NPWT and when to stop NPWT are keys to an effective plan.[8]

Prepare the wound environment	Before NPWT, debride wound
	**Effective debridement may:** • Reduce biochemical imbalance[10] • Reduce bacterial burden[10] • Optimise healing potential[10]
Use NPWT	**Optimise healing with NPWT - Mechanisms of Action[3]**
	• Remove exudate • Assist in wound contraction • Stimulate granulation tissue • Protect from outside contaminants • Increase vascular perfusion • Encourage proliferation of epithelial cells[35] • Maintain a moist wound environment  Foam Gauze
Time management	**Know when to stop or change treatment**
	• Established goal of therapy has been met[3,8] • No improvement or reduction in wound volume has been documented consecutively for 2 weeks[8] • Individual patient and wound considerations may vary clinical decision to discontinue NPWT[8]

General therapy considerations

Wound assessment

Success of the negative pressure wound therapy (NPWT) treatment depends heavily upon the quality of the clinical wound assessment. The patient and their 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.[11] 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. Trauma shouldn't occur to the granulation tissue with dressing removal. A non-adherent dressing or a contact layer may be used to reduce pain or where the risk of tissue in-growth is present.[3]

Epithelialization: amount and description

Epithelialization is thin and often noted to be shiny or silver in appearance and may be hard to see. 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

The use of NPWT in wounds with necrotic tissue with eschar present is contraindicated.

Necrotic tissue is devitalised tissue and often appears black or brown, hard and dry. Soft or boggy necrotic tissue should be assessed for infection.

NPWT, along with the autolytic environment established by the transparent film, may result in a decrease in necrotic slough.[13]

Slough

Slough is necrotic or devitalised tissue that is yellow in appearance and can be dry or moist.

Exudate: type, amount and consistency

Assess wound exudate for type, amount, colour 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.

Odour: 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 may likely have an unpleasant odour. This odour is not a direct indication of wound infection. Remove dressing and cleanse wound per facility protocol. If odour persists, assess for wound infection, and if required treat and increase frequency of dressing changes until odour is under control. The use of an antimicrobial wound contact layer may be used to reduce bacterial burden.

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 recommended pressure range is -40 to -120 mmHg which should allow for pressure adjustments.

When using the RENASYS-F Foam Dressing Kit, tissue adherence may be reduced by use of a non-adherent wound contact layer and/or increasing the frequency of the dressing changes to decrease tissue in-growth.[3]

Consider utilising RENASYS-Gauze dressing kit. See choosing a wound filler.

RENASYS◇ INTRODUCTION

RENASYS Negative Pressure Wound Therapy System (NPWT)

Devices

RENASYS TOUCH

RENASYS GO

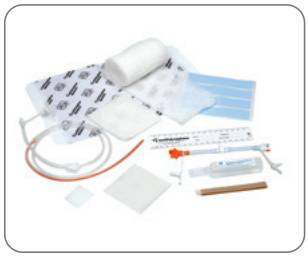
Dressing Kits with Soft Port

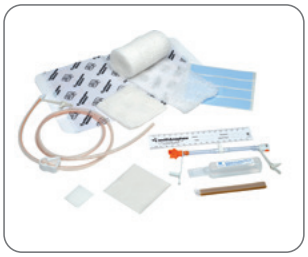
RENASYS AB Abdominal Dressing Kit with Soft Port

RENASYS-F Foam Dressing Kits with Soft Port

RENASYS-G Gauze Dressing Kits with Soft Port

Drain kits





NOTE: Full device operation is found in the User Manual for each RENASYS device

Description

RENASYS◇ NPWT devices are designed to provide NPWT to a closed environment over a wound, in order to evacuate exudate from the wound site to a disposable canister, which may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudate and infectious materials.

Important information - Monitoring NPWT

Carefully monitor the patient, pump, and dressing frequently to determine if there are any signs of bleeding, exudate accumulation (pooling), infection, maceration, or loss of negative pressure wound therapy (NPWT). The frequency should be determined by the clinician based on individual characteristics of the patient and wound. NPWT pumps are not designed to detect or issue an alarm condition based on the presence of bleeding or pooling. These conditions may only be detected by frequent monitoring.

The recommended therapeutic pressure range is -40 to -120mmHg. Pressure setting is a clinical decision each healthcare provider must make, based on an individual assessment of the particular patient and wound. White Foam may deliver a reduced level of negative pressure through long sections of the foam, for example tunnels.

Special attention to the risks of bleeding or loss of NPWT should be considered when prescribing for use in the Home Environment.

NPWT may be impacted by various conditions related to system configuration, set-up and individual characteristics of the patient and wound (e.g. exudate characteristics, patient anatomy). Alignment of the port to the opening in the drape, use of a bridging technique and choice of dressing configuration based on wound characteristics may impact NPWT vacuum delivery over the course of therapy.

Exudate volume, viscosity and consistency may influence fluid removal or occlusion formation. A full canister, incorrect canister orientation and pump/tubing height relative to the wound can contribute to loss of NPWT and exudate accumulation within the wound, which could lead to maceration, infection or unrecognised bleeding.

Monitor the wound for infection and ensure that all wound filler is removed at each dressing change to reduce the risk of infection. Skin grafts should be closely monitored to ensure NPWT is being delivered. Review contraindications, warnings and precautions before use.

Indications for use

The RENASYS NPWT system is indicated for patients who would benefit from a suction device NPWT (Negative Pressure Wound Therapy) as it may promote wound healing via removal of fluids, body fluids, wound exudate and infectious materials.

Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Sub-acute and dehisced wounds
- Pressure injuries and diabetic ulcers
- Flaps and grafts
- Partial thickness burns

Contraindications

The use of the RENASYS Negative Pressure Wound Therapy 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 and unexplored fistulas
- Exposed anastomotic sites

Warnings

Carefully monitor patients for signs of bleeding, which may lead to interruption in therapy and haemodynamic instability. If such symptoms are observed, immediately discontinue therapy, take appropriate measures to control bleeding and contact treating clinician.

1. Patients suffering from difficult haemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using haemostatic products that, if disrupted, may increase the risk of bleeding.
2. Do not use directly 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 closer under the action of negative pressure.
3. NPWT has not been studied on paediatric patients. Patient size and weight should be considered when prescribing the device.
4. Foam or gauze must not be tightly packed or forced into any wound area. Over-packing may interfere with distribution of NPWT evenly across the wound. This may decrease the ability of the wound to properly contract and permit exudate to remain in the wound. Do not place foam into blind or unexplored tunnels.
5. In the event that defibrillation is required, disconnect the RENASYS◇ pump from wound dressing prior to defibrillation. Remove wound dressing only if its location will interfere with defibrillation.
6. RENASYS pumps are not MRI compatible. Do not bring device into MRI suite. Prior to entering MRI suite, disconnect pump from dressing. Dressing can remain intact on patient.
7. The RENASYS system is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).
8. When operating, transporting or disposing of pump and accessories, there is a risk of infectious liquids being aspirated or contamination of system assembly through incorrect use. Universal precautions should be observed whenever working with potentially contaminated components or equipment.
9. The RENASYS System is provided non-sterile and should not be placed within a sterile field unless the packaging is marked as sterile.

Precautions

1. More frequent pump and wound dressing monitoring, should be taken for patients who are or may be:
   - Suffering from infected blood vessels
   - Receiving anticoagulant therapy or platelet aggregation inhibitors, in addition to patients with intrinsic coagulation problems such as low platelet counts
   - Actively bleeding or have friable blood vessels or organs
   - Suffering from abnormal wound haemostasis
   - Untreated for malnutrition
   - Non-compliant or combative
   - Suffering from wounds in close proximity to blood vessels or friable fascia

When monitoring patients for delivery of therapy, ensure wound dressing is free of air leaks, fully compressed and firm to the touch. Ensure that pressure indicated on pressure gauge reflects set pressure on pressure selector knob.

On RENASYS GO and RENASYS TOUCH pumps, ensure that the pressure reading indicated on the device screen reflects the desired level of negative pressure.

2. As a condition of use, the RENASYS System should only be used by qualified and authorised personnel. User must have necessary knowledge of the specific medical application for which NPWT is being used.
3. The dressing seal may be lost or pooling may occur, without alarm activation, when an occlusion forms on the wound side of the dressing. Viscous, purulent or serosanguineous drainage may contribute to occlusion of the dressing. Regular monitoring of pump and dressing is required to ensure full delivery of therapy and exudate removal. Ensure the wound dressing is free of air leaks, fully compressed and firm to the touch whenever therapy is active.
4. Underlying structures, such as bone, tendons, ligaments and nerves should be covered with natural tissue or a non-adherent dressing layer prior to applying the NPWT dressing to ensure protection and minimise the risk of damage from direct contact with the dressing.
5. To minimise the risk of bradycardia, do not place NPWT in proximity to the vagus nerve.

6. In the event a patient with spinal cord injury experiences autonomic dysreflexia, discontinue use of NPWT and immediately seek medical assistance.
7. When treating enteric fistulas, do not place NPWT dressing in direct contact with exposed bowel. Cover the wound bed, including fistula opening, with non-adherent gauze or with one layer of saline moistened gauze. During the course of treatment the patient's fluid levels must be closely monitored.
8. Avoid use of circumferential dressings except in cases of oedema or heavily exuding extremities, where this technique may be necessary to maintain a seal. Consider using multiple drapes to minimise risk of decreased distal circulation. Regularly assess distal pulses, and discontinue therapy if changes in circulation are detected.
9. Monitor patient for any signs of local or systematic infection. Infected wounds may require more frequent dressing changes. As NPWT is not intended to directly treat infection, if there are any signs of systematic infection at wound area, contact treating clinician immediately.
10. If multiple pieces of foam or gauze are needed to fill the wound profile, count and record how many pieces are present to ensure all pieces are removed at a dressing change to minimise the risk of retention and possible infection.
11. NPWT should remain on for duration of treatment. The length of time a patient may be disconnected from the RENASYS◇ pump is a clinical decision based on individual characteristics of the patient and wound. Factors to consider include location of wound, volume of drainage, integrity of dressing seal, assessment of bacterial burden and patient's risk of infection.
12. Do not use a dressing kit with breached or damaged packaging.
13. Use of NPWT presents a risk of tissue in-growth. Tissue in-growth may be reduced by reducing therapy pressure, using a wound contact layer or increasing the frequency of dressing changes.
14. NPWT should not be painful. If the patient reports discomfort, consider reducing pressure setting and use of a wound contact layer. Pressure setting is a clinical decision based on individual characteristics of the patient and wound. Factors to consider include location of wound, volume of drainage and integrity of dressing seal.
15. Maintain regular monitoring of the pump and wound site during therapy to ensure therapeutic treatment and patient comfort.
16. When bathing or showering patient must disconnect from the RENASYS pump, protecting both ends of the Soft Port tubing using tethered caps. Ensure aeration disc located near quick click connector is free of moisture before reactivation of therapy to ensure proper alarm functionality and prevent interruption in therapy.
17. If any liquids penetrate the pump, discontinue use and return to your Smith & Nephew authorised provider for service.
18. CT scans and x-ray have the potential to interfere with some electronic medical devices. Keep the RENASYS pump out of x-ray or scanner range.
19. The RENASYS Negative Pressure Wound Therapy system is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
20. AC mains power can only be removed by disconnecting power cord or AC power adaptor. Take care in positioning the pump to allow access to cord receptacle.
21. If power cord is damaged, wires are frayed or exposed, do not use power cord. Contact your Smith & Nephew representative for a replacement cord.
22. RENASYS canisters and dressing kits are single use devices. Do not reuse.
23. Do not apply SECURA◇ No-Sting Barrier Film wipes directly to open wounds. SECURA No-Sting Barrier Film is flammable. Use in a well ventilated area. Avoid using around flames and sources of ignition. Keep out of reach of children. For external use only.
24. As with all adhesive products, apply and remove dressing carefully from sensitive or fragile skin to avoid blistering and skin stripping, especially after frequent dressing changes. Use of skin sealant may assist with protection of periwound skin.
25. If patient must be disconnected from the pump, the ends of the RENASYS Soft Port and canister tubing should be protected using tethered caps to avoid leakage of fluid and cross contamination.

NOTE: Do not wait for the canister over-capacity alarm to activate to change canister.

Precautions specific to RENASYS◇ TOUCH device

1. Ensure canister tubing and RENASYS Soft Port are installed completely and without any kinks to avoid leaks or blockages in vacuum circuit. Position pump and tubing appropriately to avoid risk of a trip hazard.
2. Place device and tubing level with or below the wound. This will ensure the prescribed level of therapy is delivered.
3. RENASYS TOUCH pump is only to be used with Smith & Nephew authorised components. Use of any other products has not been proven safe and effective with RENASYS TOUCH.
4. In the event of heavy or viscous drainage with sediment or when blood is present, regular monitoring and more frequent dressing changes may be required to reduce the risk of interruption of therapy, maceration, infection,and ensure proper exudate removal.
5. For patients with high risk of bleeding, use 300ml canister. Ensure the 300ml canister viewing window is checked frequently for signs of bleeding.

Precautions specific to RENASYS GO device

1. In the event of heavy or viscous drainage with sediment or when blood is present, regular monitoring and more frequent dressing changes may be required to reduce the risk of interruption of therapy, maceration, infection, and ensure proper exudate removal.
2. For patients with high risk of bleeding, use 300ml canister. Ensure the 300ml canister viewing window is checked frequently for signs of bleeding.
3. RENASYS GO pump is only to be used with Smith & Nephew authorised components. Use of any other products have not been proven safe and effective with RENASYS GO.
4. Ensure canister tubing and RENASYS Soft Port are installed completely and without any kinks to avoid leaks or blockages in vacuum circuit. Position pump and tubing appropriately to avoid risk of a trip hazard. Pump and system tubing should be positioned no more than 19 inches or 50cm higher than the wound to ensure optimisation of therapy and prevent therapy interruption.
5. Canisters should be changed at least once a week, whenever there is a change in patient or in the event that canister contents reach maximum volume indication (300ml or 750ml fill line).

NOTE: Do not wait for the canister over-capacity alarm to activate to change canister.

Notes

RENASYS◇ GENERAL THERAPY CONSIDERATIONS

Choosing a wound filler and interface

Smith & Nephew offers the clinician flexibility with a choice of dressing kits for use with Negative Pressure Wound Therapy (NPWT). The following dressing kits are available: RENASYS Foam with Soft Port, RENASYS Gauze with Soft Port, a selection of drain kits and RENASYS Abdominal kit with Organ Protection Layer (OPL).

The factors to consider when choosing a dressing kit are based on the patient, the wound characteristics and clinical judgement of the healthcare professional (HCP).

Clinical studies have demonstrated that the overall healing rates, defined as percent reduction in wound volume/surface area per week, are similar with both gauze and foam.[3,14,15]

It is anticipated that the HCP can expect similar efficacy from either type of filling.

The following guidelines have been developed based on feedback and insights from HCPs who have used all RENASYS dressing kit options.

Factors to consider include:

- Wound size and volume
- Contour of wound bed
- Appearance of wound bed/tissue type
- Amount and type of exudate
- Anatomical location of wound e.g. weight bearing area
- Patient comfort and preference
- Caregiver skills

NOTE: It is important that a holistic assessment is made of the patient and wound characteristics and that a decision is not just made on only one factor alone. The above list is not exhaustive and local clinical judgement must always be used. Always consult the IFU (Instruction for Use) and safety information.

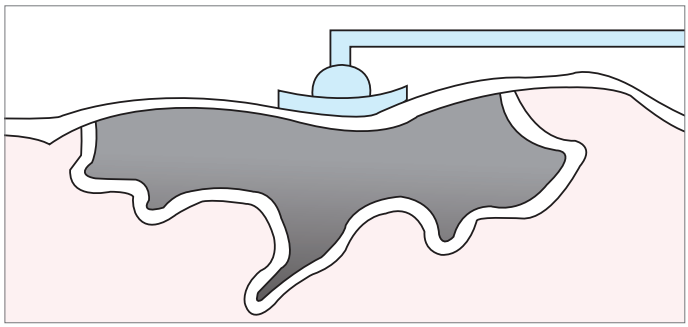
Wound characteristics

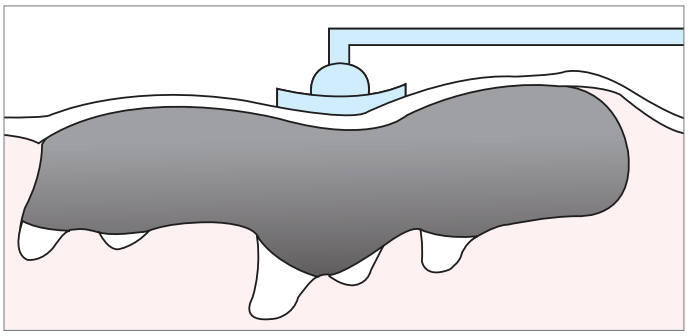
Wound size and volume

- Small to moderate size wounds with shallow depth: both foam and gauze may be used with similar ease of application.[8]
- Moderate to large surface area wounds with shallow depth and irregular shape: gauze is generally considered easier to apply.[8]
- Moderate to large surface area wounds with deep, regular shape: foam may be considered easier to use.[8]

Wound contour

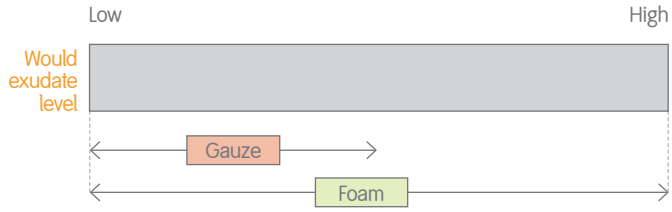
- Wound bed contour[16]





Gauze wound filler easily maintains contact with an irregular surface. Foam wound filler may not intimately contact irregular shape spaces in wound bed. In this case, gauze and foam may be used in combination. See combination therapy page 15.

The choice of wound filler will be influenced by the amount and consistency of wound exudate

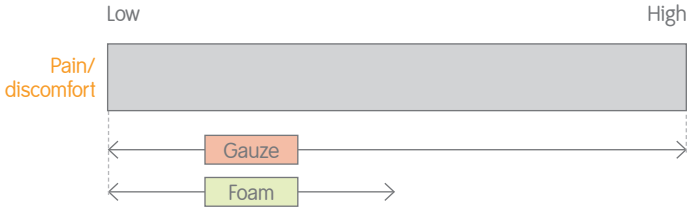


Precautions specific to gauze

1. Use of gauze as a filler in wounds that are in a weight bearing location or have moderate to heavy drainage may challenge the transfer of fluid and vacuum. Foam is recommended in these wounds. RENASYS◇ Foam and Gauze filler may be combined within the same wound when tunnelling or undermining is present. Gauze may be used in the areas of undermining or tunnelling, with foam placed in the remainder of the wound cavity. In wounds with large amounts of exudate a wound interface (non-adherent layer) is generally not recommended.
2. If it is necessary to use gauze in a wound with heavy or viscous exudate, select a RENASYS flat drain accessory kit if available. Ensure the drain is placed close to the wound bed over a single layer of gauze. Several published studies have provided evidence for the successful use of NPWT drains in appropriate circumstances.[15,18,19]
3. Ensure gauze is placed into the contours of the wound rather than tightly packed into the wound. This will aid fluid transference.

Patient comfort

Pain is a very subjective experience and will vary with each patient. Research has shown that patients report less pain with gauze.[19]*



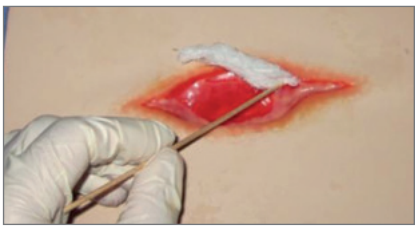
*Compared to foam

Combination therapy

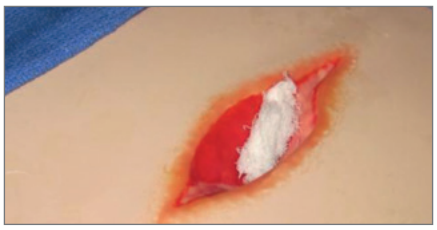
Gauze/foam combination therapy:

RENASYS Foam and Gauze filler may be combined within the same wound when tunnelling or undermining is present.[17] Gauze may be used in the areas of undermining or tunnelling, with foam placed in the remainder of the wound cavity.

Combination use:

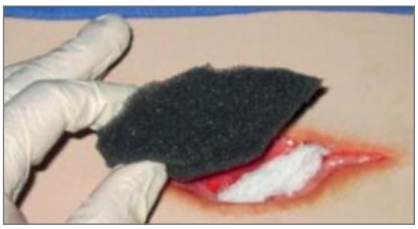


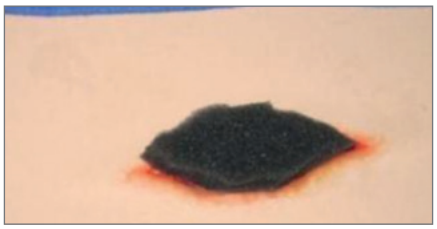
1. When using gauze in a tunnel or undermining area, ensure a tail is exposed for ease of removal and/or sufficient contact with the foam layer.



2. Visual representation of gauze placed into undermined area.

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





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

NOTE: Contact must be maintained between the two materials.

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

Considerations for device selection

The RENASYS◇ Family, RENASYS GO and RENASYS TOUCH pumps can be used on a variety of wounds.

The RENASYS TOUCH device has a touchscreen display which is designed to be easy to navigate and has adjustable volume, compression rates and therapy modes.[21,22] The device is able to deliver therapy from -25 to -200mmHg and intermittent therapy from 0 to -200mmHg with adjustable cycle times. RENASYS TOUCH is able to provide comprehensive therapy data on the device and provides access to quick reference guides to provide trouble shooting assistance.[23]

In a independent randomised clinical study the efficacy and clinical effectiveness of the RENASYS GO device was found to be comparable with an established NPWT system, with no statistically significant differences reported in the clinical outcomes.[24]

Refer to specific quick reference guides, Instructions for use (IFU) or specific product user manuals for additional instructions. Please see page 83 of the appendix for product components and ordering.

The RENASYS TOUCH device:

- All sizes of wounds small to large, including open abdomen
- Can be used with RENASYS dressing kits including Abdominal kit
- Variable Intermittent Mode, Variable compression rate and dressing leakage meter
- History log recording pump running time, mode selection and alarms
- Variety of care settings
- Minimises the impact on patient lifestyle due to size and provides 10 to 16 hours therapy when operating from -25mmHg to -120mmHg.[25]
- On-screen help on the pump

The RENASYS◇ GO device is specifically designed to address:

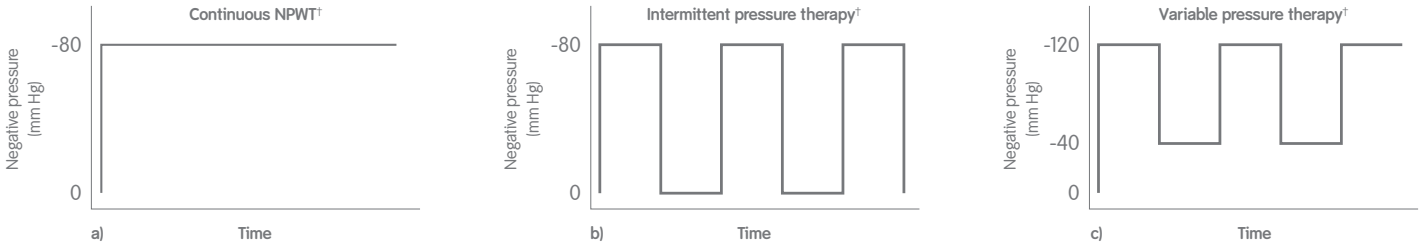
- A broad range Negative Pressure Wound Therapy (NPWT) applications
- Variety of care settings
- Minimises impact on patient lifestyle due to size and provides 20 hours therapy when operating up to -120mmHg.[26]

NOTE: Not designed to be used with RENASYS AB Abdominal Dressing Kit with Soft Port.

Overview of NPWT modes

NPWT can be delivered to the wound bed using 3 modes of delivery; continuous, intermittent or adjustable.

- Continuous: Pressure is applied constantly
- Intermittent: Pressure is repeatedly switched on and off alternating between 0 and set pressure
- Variable Intermittent Mode: Pressure is varied between two levels (set pressure and low pressure) maintaining a negative pressure environment throughout the therapy.



RENASYS® Touch

RENASYS GO

Experimental studies have shown improvements in the rate of granulation tissue formation, wound contraction and blood flow with intermittent and variable NPWT compared with continuous NPWT.[27]

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

Intermittent therapy is not recommended for:

- Highly exudating wounds
- Wounds with tunnels or undermining
- Wounds in difficult areas where maintaining a seal is problematic
- Patients who experience pain during variable intermittent mode therapy

NOTE: The RENASYS TOUCH is able to deliver intermittent and adjustable intermittent NPWT using tailored time settings defined by the clinician.

The RENASYS GO are only able to provide intermittent therapy at a 5 minute on 2 minute off interval.

†Pressure range on graphs are for example purposes only and not a recommendation of therapy setting(s) to be used in a clinical situation

RENASYS◇ portfolio – pumps and canisters

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 TOUCH

- Pump
- Power cord
- Single patient use carrying case and strap available
- IV Pole/Bed rail clamp available

RENASYS GO

- Pump
- Power cord
- Single Use carrying case and strap available

CAUTIONS: Canister kits are single use non sterile.

1. Always use the smallest canister volume possible.
2. DO NOT use the 800ml canisters on patients with high risk of bleeding.
3. Canisters should be changed at least once a week, whenever there is a change of patient or in the event that the canister contents reach maximum volume indication. Do not wait for canister over-capacity alarm activation to change canister.

See appendix for product components and ordering.

300 ml TOUCH-Canister

- Sealed canister
- With or without solidifier
- Canister tubing
- Kickstand

800 ml TOUCH-Canister

- Sealed canister
- With solidifier
- Canister tubing

RENASYS GO Canister (300ml)

- Sealed canister
- Solidifier
- Canister tubing

RENASYS◇ GO Large Canister (750ml)

- Sealed canister
- Solidifier
- Canister tubing

Pump/Canister optimisation

RENASYS◇ TOUCH

1. Device and canister should remain in an upright orientation to maximise canister volume and optimise complete blockage/ canister over capacity alarm.

RENASYS GO

1. Device and canister should remain in an upright orientation to maximise canister volume and optimise complete blockage/ canister over capacity alarm. The RENASYS GO device should be placed no higher than 19 inches (50cm) above the wound when possible.

RENASYS canisters

Refer to instructions for use provided with canisters for additional information on canister installation and use.

1. Canisters are non-sterile and should not be used in the sterile field.
2. Canisters are single use devices. DO NOT REUSE.
3. Canisters should be changed at least once a week, whenever there is a change in patient or in the event the canister contents reach maximum volume indication (250ml, 300ml, 750ml or 800ml fill line).

NOTE: Do not wait for the canister over capacity alarm to change canister.

Important! The in-line bacterial overflow guard must be inserted past the fourth ridge to a point approximately halfway between the fourth ridge and the face of the in-line bacterial overflow guard. Failure to fully insert may result in a leak in the system, which may impact device alarm functionality.

Dressing changes

Refer to instructions for use provided with the RENASYS◇ dressing kits for additional information on dressing use and maintenance.

1. Foam dressings should be changed every 48 to 72 hours after initial application of therapy. If no leak is present and the patient is comfortable, dressing changes should occur no less than 3 times per week.
2. Gauze dressings should be changed 48 hours after initial application of therapy. If no leak is present and patient is comfortable, dressing changes should occur 2–3 times per week.
3. In the event of heavy or viscous drainage, drainage with sediment, or when blood is present, regular monitoring and more frequent dressing changes may be required.
4. When dressing a wound involving difficult to seal anatomy or exposure to external moisture, frequent inspection of the dressing is recommended to ensure a seal is maintained. Ensure wound dressing is fully compressed and firm to the touch.
5. Ensure all wound filler material placed in wound has been removed before redressing wound. If foam dressing adheres to wound, apply normal saline into wound dressing and let it set for 15–30 minutes before gently removing foam. Appropriately discard used wound dressings observing your institution's protocol for medical waste handling.
6. As with all adhesive products, apply and remove dressing carefully from sensitive or fragile skin to avoid skin stripping, especially after frequent dressing changes. Use of skin sealant may assist with protection of periwound skin.
7. Monitor patient for any signs of local or systemic infection. Infected wounds may require more frequent dressing changes. If there are any signs of systemic infection or advancing infection at wounded area, contact treating clinician immediately.
8. If the RENASYS pump activates a complete blockage alarm, inspect the dressing and canister tubing for any blockage. If a blockage cannot be identified or resolved, replace the pump's canister first, then remove the dressing and Soft Port, replacing as necessary.

NPWT pressure settings

General guidelines:

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

NOTE: Recommended pressure range for the RENASYS NPWT Systems is -40mmHg to -120mmHg.

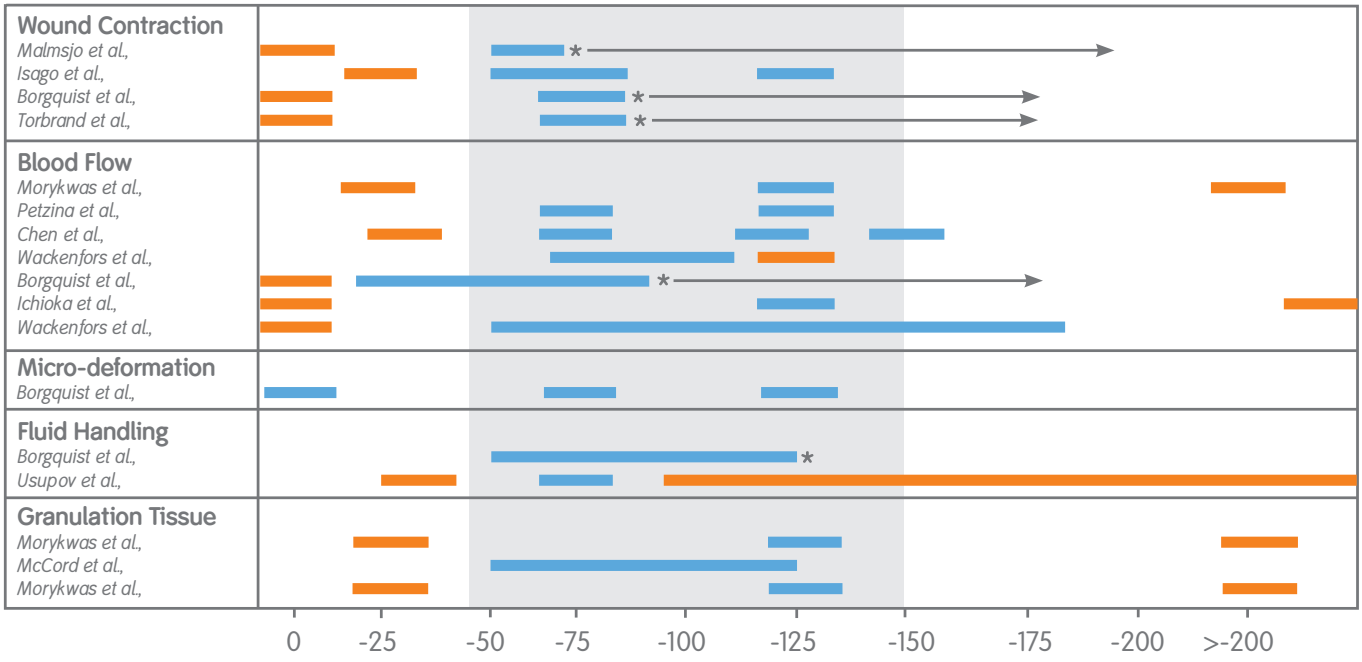
- If a patient experiences discomfort, it may help to reduce the pressure level.
- An increase in the pressure may be necessary according to size of wound, viscosity of exudate, amount of exudate and clinical judgement of desired wound outcomes.
- Anatomical location and tissue pliability may also influence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

Negative Pressure Wound Therapy (NPWT) should remain on for duration of treatment. If patient must be disconnected form the pump, the ends of the Soft Port and canister tubing should be protected using tethered caps. The length of time a patient may be disconnected from the pump is a clinical decision based on individual characteristics of patient and wound. Factors to consider include location of wound, volume of drainage, integrity of the dressing seal, assessment of bacterial burden and patient's risk of infection.

Delivering the right pressure level

With respect to pressure levels, an independent International Negative Pressure Wound Therapy (NPWT) Expert Panel convened to develop evidence based recommendations describing the use of NPWT.[3]

They recommended that NPWT be used within a therapeutic range of -40mmHg to -130mmHg. The recommended pressure settings for RENASYS◇ NPWT devices fall within this range.



Adapted from *Birke-Sorensen H et al.* (2011)[3]

Impact of varying negative pressure on mode of action of NPWT[3]

Orange bars indicate pressure where no effect or detrimental effects have been observed.

Blue bars indicate where beneficial effects have been observed. **The shaded area** demonstrates the therapeutic range of negative pressure levels based on the majority of studies. Studies on intact volunteer skin excluded.

Continuous versus intermittent therapy:

An additional aspect of pressure setting is the choice between continuous, intermittent and adjustable delivery of pressure. The RENASYS EZ and GO system delivers intermittent therapy at a cycle of 5 minutes on and 2 minutes off, whereas RENASYS TOUCH offers variable maximum and minimum pressures and times. The NPWT setting should be determined by prescribing clinician and tailored to the individual wound for optimal effects.

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

RENASYS◇ DRESSING SELECTION AND APPLICATION

Considerations for use of variable intermittent or adjustable therapy

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

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

NOTE: Most effective delivery of variable pressure is thought to occur when pressure cycles between a 'high' level of pressure within the therapeutic range of -40mmHg to -120mmHg) to a 'low' pressure of below the therapeutic range of NPWT (i.e. below -40mmHg).[29]

Consideration for use of continuous therapy

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

In patients who would benefit from intermittent or adjustable therapy but who experience wound pain, please select the adjustable option.

Pain during the application of NPWT may be experienced more frequently during the on and off cycle of intermittent therapy. Less pain is experienced with adjustable intermittent therapy.[28]

RENASYS Soft Port – considerations for use

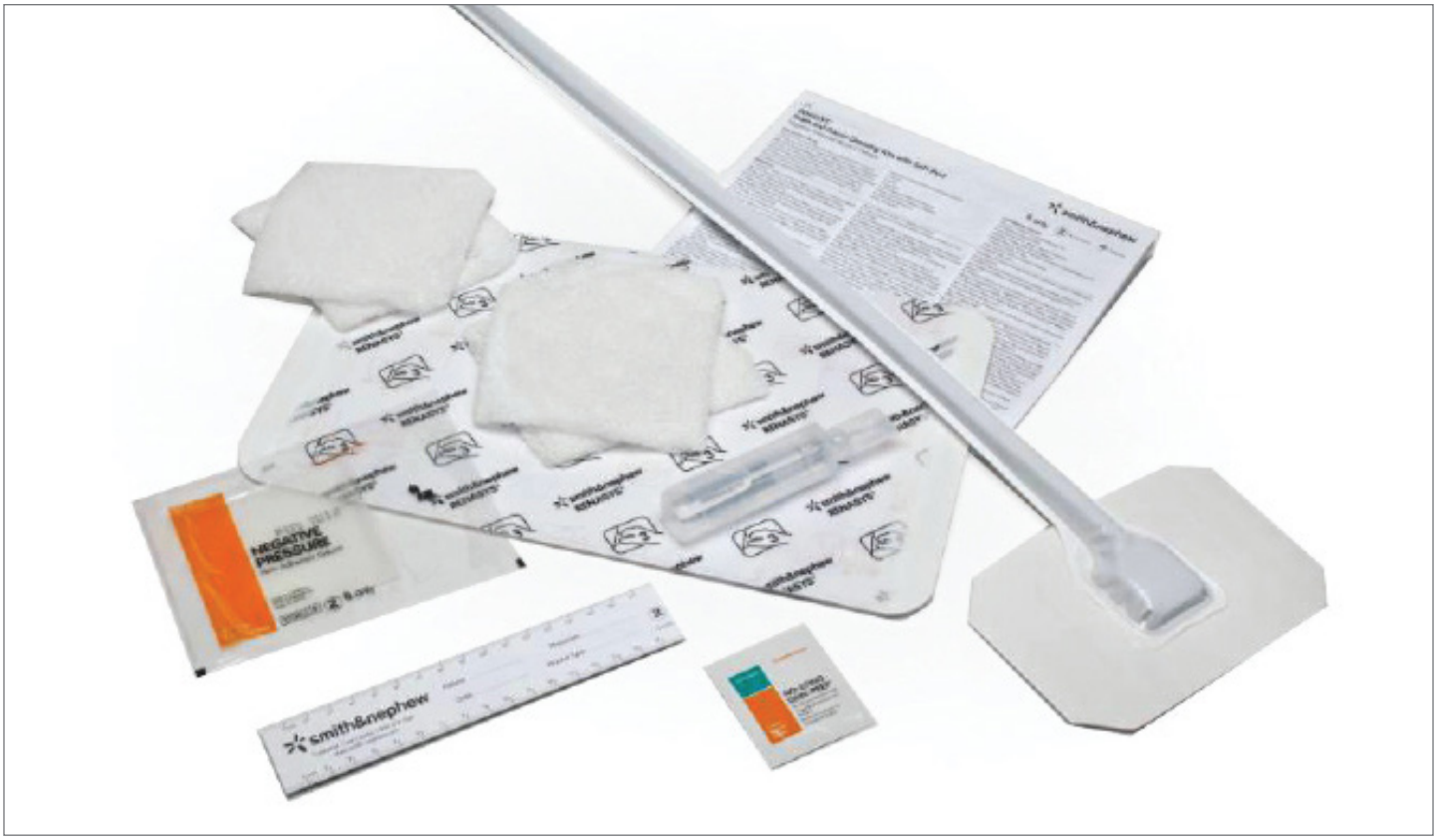
- It is important to align the opening of the Soft Port with the cut hole in the transparent film to ensure a good seal and decrease the risk for a false blockage alarm.
- The Soft Port opening is 1.5cm in diameter. It is important that the cut hole in the transparent film is no less than 2cm in diameter.
- When cutting the hole in the transparent film remove any loose edges from the film to prevent aspiration into the Soft Port, possibly causing a false blockage alarm.
- Under normal circumstances, it should not be necessary to bridge away from the wound. If there is a concern that the Soft Port may create pressure at the wound, due to the wound's location and condition, or if the wound is smaller than the soft port opening (1.5cm), utilise the bridge technique on page 52.

Healthcare professional orders

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

All treatment orders should include:

- Size and/or wound measurements
- Smith & Nephew wound dressing kit type
- Vacuum settings (recommended therapeutic range is -40 to -120mmHg)
- Frequency of dressing changes
- Adjunctive dressings



RENASYS◇-G Gauze Dressing with Soft Port application technique

Refer to the RENASYS-G Gauze dressing kit Instructions for Use leaflet for further information.

Use clean or sterile/aseptic techniques protocol. Only use RENASYS dressing kits approved for use with the RENASYS system.

See page 98 of the appendix for kit sizes and components.

Precautions

1. More frequent pump and wound dressing monitoring, should be taken for patients who are or may be:
   - Suffering from infected blood vessels
   - Receiving anticoagulant therapy or platelet aggregation inhibitors, in addition to patients with intrinsic coagulation problems such as low platelet counts
   - Actively bleeding or have friable blood vessels or organs
   - Suffering from difficult wound haemostasis
   - Untreated for malnutrition
   - Noncompliant or combative
   - Suffering from wounds in close proximity to blood vessels or delicate fascia

When monitoring patients for delivery of therapy, ensure wound dressing is free of air leaks, fully compressed and firm to the touch.

On RENASYS GO and RENASYS TOUCH pumps, ensure that the pressure reading indicated on the device screen reflects the desired level of negative pressure.

2. As a condition of use, pump should only be used by qualified and authorised personnel. User must have necessary knowledge of the specific medical application for which NPWT is being used.
3. For patients with high risk of bleeding use RENASYS TOUCH or RENASYS GO 300ml canisters.
4. The dressing seal may be lost or pooling may occur, without alarm activation, when an occlusion forms on the wound side of the dressing. Viscous, purulent or serosanguineous drainage may contribute to occlusion of the dressing. Regular monitoring of the pump and dressing is required to ensure full delivery of therapy and exudate removal. Ensure the wound dressing is free of air leaks, fully compressed and firm to the touch whenever therapy is active.
5. Underlying structures, such as bone, tendons, ligaments and nerves should be covered with natural tissue or a non-adherent dressing layer prior to applying the NPWT dressing to ensure protection and minimize the risk of damage from direct contact with the dressing.
6. To minimise risk of bradycardia, do not place NPWT in proximity to the vagus nerve.
7. In the event a patient with spinal cord injury experiences autonomic dysreflexia, discontinue use of NPWT and immediately seek medical assistance.
8. When treating enteric fistulas, do not place NPWT dressing in direct contact with exposed bowel. Cover wound bed, including fistula opening, with non-adherent gauze or with one layer of saline moistened gauze. During the course of treatment, patient's fluid levels must be closely monitored.
9. Avoid use of circumferential dressings except in cases of oedema or heavily exuding extremities, where this technique may be necessary to maintain a seal. Consider using multiple drapes to minimise risk of decreased distal circulation. Regularly assess distal pulses, and discontinue therapy if changes in circulation are detected.
10. Monitor patient for any signs of local or systemic infection. Infected wounds may require more frequent dressing changes. As NPWT is not intended to directly treat infection, if there are any signs of systemic infection or advancing infection at wound area, contact treating clinician immediately.
11. If multiple pieces of gauze are needed to fill the wound profile, count and record how many pieces are present to ensure all pieces are removed at a dressing change to minimise the risk of retention and possible infection.
12. NPWT should remain on for duration of treatment. The length of time a patient may be disconnected from the pump is a clinical decision based on individual characteristics of patient and wound. Factors to consider include location of wound, volume of drainage, integrity of dressing seal, assessment of bacterial burden and patient's risk of infection.
13. Do not use a dressing kit with breached or damaged packaging.
14. Use of NPWT presents risk of tissue in-growth. Tissue in-growth may be reduced by decreasing therapy pressure, using a wound contact layer or increasing the frequency of dressing changes.
15. NPWT should not be painful. If patient reports discomfort, consider reducing pressure setting and use of a wound contact layer. Pressure setting is a clinical decision based on individual characteristics of patient and wound. Factors to consider include location of wound, volume of drainage and integrity of dressing seal.

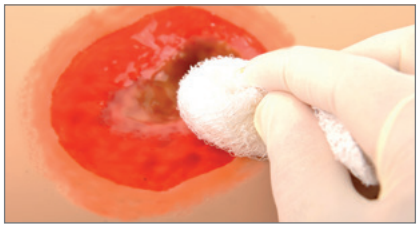
16. Maintain regular monitoring of the pump and wound site during therapy to ensure therapeutic treatment and patient comfort.
17. RENASYS◇ pumps are only to be used with Smith & Nephew authorised components. Use of any other products have not been proven safe and effective with RENASYS pump.
18. Ensure canister tubing and RENASYS Soft Port are installed completely and without any kinks to avoid leaks or blockages in vacuum circuit. Position pump and tubing appropriately to avoid risk of a trip hazard. Pump and system tubing should be positioned level with or below the wound for the RENASYS TOUCH pumps and no more than 19in or 50cm higher than the wound for RENASYS GO pump to ensure optimisation of therapy and prevent therapy interruption. When bathing or showering patient must disconnect from pump, protecting both ends of Soft Port tubing using tethered caps. Ensure aeration disc located near orange quick click connector is free of moisture before reactivation of therapy to ensure proper alarm functionality and prevent interruption in therapy.
19. If any liquids penetrate pump, discontinue use and return to your Smith & Nephew authorised provider for service.
20. CT scans and x-ray have the potential to interfere with some electronic medical devices. Keep pump out of x-ray or scanner range.
21. The RENASYS Negative Pressure Wound Therapy system is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
22. AC mains power can only be removed by disconnecting power cord. Take care in positioning pump to allow access to cord receptacle.
23. If power cord is damaged, wires are frayed or exposed, do not use power cord. Contact your Smith & Nephew representative for a replacement cord.
24. Canisters should be changed at least once a week, whenever there is a change of patient or in the event the canister contents reach maximum volume indication. Do not wait for canister over-capacity alarm activation to change canister.
25. Canisters are single-use devices. Do not reuse.
26. Do not apply SECURA◇ No-sting barrier film wipes directly to open wounds. SECURA No-sting barrier film is flammable. Use in a well ventilated area. Avoid using around flames and sources of ignition. Keep out of reach of children. For external use only.
27. As with all adhesive products, apply and remove dressing carefully from sensitive or fragile skin to avoid blistering and skin stripping, especially after frequent dressing changes. Use of skin sealant may assist with protection of peri-wound skin.
28. If patient must be disconnected, the ends of the RENASYS Soft Port and canister tubing should be protected using tethered caps to avoid leakage of fluid and cross contamination.
29. The RENASYS -G Gauze dressing kit 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.

Considerations specific to gauze

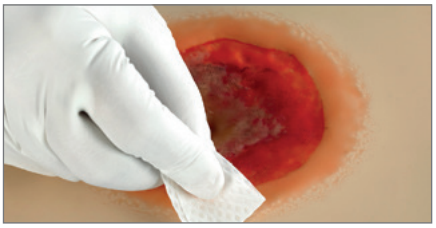
1. Use of gauze as a filler in wounds that are in a weight bearing location or have moderate to heavy drainage may challenge the transfer of fluid and vacuum. Foam is recommended in these wounds.
2. RENASYS◇ foam and gauze filler may be combined within the same wound when tunnelling or undermining is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

Clean and debride

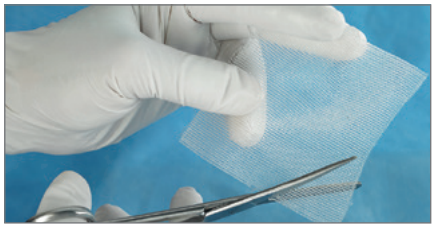
Use clean or aseptic techniques for application, according to your institutional protocol. Thorough wound cleansing should occur with each dressing change.



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



2. If desired, protect the peri-wound skin from exposure to moisture and adhesive through the use of a skin sealant. Allow the skin sealant to dry fully prior to placement of the transparent film.



3. If desired, a non-adherent dressing may be applied. Trim a single layer of non-adherent gauze and lay across wound bed.

Dress wound with gauze

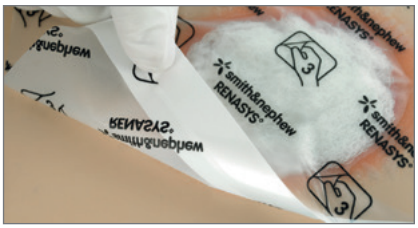
Review precautions specific to foam and gauze before continuing. It is critical that gauze is not forced into any wound, or placed within an unexplored tunnel.

1. Apply a layer of saline-moistened antimicrobial gauze to wound bed (saline not included in RENASYS◊-G Sterile dressing Kit.)

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

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

Seal the wound



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

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

NOTE: Avoid stretching or pulling the transparent film to minimise tension or trauma to the periwound skin.

Recommendations:

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

Apply RENASYS◊ Soft Port:

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

2. If desired, protect the peri-wound skin from exposure to moisture and adhesive through the use of a skin sealant. Allow the skin sealant to dry fully prior to placement of the transparent film.

3. If desired, a non-adherent dressing may be applied. Trim a single layer of non-adherent gauze and lay across wound bed.

4. Smooth the dressing down while removing the RENASYS Soft Port's top stabilisation frame.

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

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

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

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

RENASYS◇-F Foam Dressing with Soft Port application technique

Refer to the RENASYS-F Foam Dressing kit Instructions for Use leaflet for further information.

Use clean or sterile/aseptic techniques protocol. Only use RENASYS dressing kits approved for use with the RENASYS system.

See page 98 of the appendix for kits sizes and components.

Precautions

1. More frequent pump and wound dressing monitoring, should be taken for patients who are or may be:
   - Suffering from infected blood vessels
   - Receiving anticoagulant therapy or platelet aggregation inhibitors, in addition to patients with intrinsic coagulation problems such as low platelet counts
   - Actively bleeding or have friable blood vessels or organs
   - Suffering from difficult wound haemostasis
   - Untreated for malnutrition
   - Noncompliant or combative
   - Suffering from wounds in close proximity to blood vessels or delicate fascia
2. As a condition of use, pump should only be used by qualified and authorised personnel. User must have necessary knowledge of the specific medical application for which NPWT is being used.
3. For patients with high risk of bleeding use RENASYS◊ EZ 250ml, RENASYS TOUCH 300ml or RENASYS GO 300ml canisters. Ensure the RENASYS EZ 250ml canister viewing window is checked frequently for signs of bleeding, as the canister holder obscures the viewing window.
4. The dressing seal may be lost or pooling may occur, without alarm activation, when an occlusion forms on the wound side of the dressing. Viscous, purulent or serosanguineous drainage may contribute to occlusion of the dressing. Regular monitoring of pump and dressing is required to ensure full delivery of therapy and exudate removal. Ensure the wound dressing is free of air leaks, fully compressed and firm to the touch whenever therapy is active.
5. Underlying structures, such as bone, tendons, ligaments and nerves should be covered with natural tissue or a non-adherent dressing layer prior to applying the NPWT dressing to ensure protection and minimise the risk of damage from direct contact with the dressing.
6. To minimise risk of bradycardia, do not place NPWT in proximity to the vagus nerve.
7. In the event a patient with spinal cord injury experiences autonomic dysreflexia, discontinue use of NPWT and immediately seek medical assistance.
8. When treating enteric fistulas, do not place NPWT dressing in direct contact with exposed bowel. Cover wound bed, including fistula opening, with non adherent gauze or with one layer of saline moistened gauze. During the course of treatment, patient's fluid levels must be closely monitored.
9. Avoid use of circumferential dressings except in cases of oedema or heavily exuding extremities, where this technique may be necessary to maintain a seal. Consider using multiple drapes to minimise risk of decreased distal circulation. Regularly assess distal pulses, and discontinue therapy if changes in circulation are detected.
10. Monitor patient for any signs of local or systemic infection. Infected wounds may require more frequent dressing changes. As NPWT is not intended to directly treat infection, if there are any signs of systemic infection or advancing infection at wound area, contact treating clinician immediately.
11. If multiple pieces of foam are needed to fill the wound profile, count and record how many pieces are present to ensure all pieces are removed at a dressing change to minimise the risk of retention and possible infection.
12. NPWT should remain on for duration of treatment. The length of time a patient may be disconnected from pump is a clinical decision based on individual characteristics of patient and wound. Factors to consider include location of wound, volume of drainage, integrity of dressing seal, assessment of bacterial burden and patient's risk of infection.
13. Do not use a dressing kit with breached or damaged packaging.

14. Use of NPWT presents risk of tissue in-growth. Tissue in-growth may be reduced by decreasing therapy pressure, using a wound contact layer or increasing the frequency of dressing changes.
15. NPWT should not be painful. If patient reports discomfort, consider reducing pressure setting and use of a wound contact layer. Pressure setting is a clinical decision based on individual characteristics of patient and wound. Factors to consider include location of wound, volume of drainage and integrity of dressing seal.
16. Maintain regular monitoring of pump and wound site during therapy to ensure therapeutic treatment and patient comfort.
17. Pump is only to be used with Smith & Nephew authorised components. Use of any other products have not been proven safe and effective with RENASYS◊ pump.
18. Ensure canister tubing and RENASYS Soft Port are installed completely and without any kinks to avoid leaks or blockages in vacuum circuit. Position pump and tubing appropriately to avoid risk of a trip hazard. Pump and system tubing should be positioned level with or below the wound for the RENASYS TOUCH pumps and no more than 19in or 50cm higher than the wound for RENASYS GO pump to ensure optimisation of therapy and prevent therapy interruption.
19. When bathing or showering patient must disconnect from pump, protecting both ends of Soft Port tubing using tethered caps. Ensure aeration disc located near orange quick click connector is free of moisture before reactivation of therapy to ensure proper alarm functionality and prevent interruption in therapy.
20. If any liquids penetrate pump, discontinue use and return to your Smith & Nephew authorised provider for service.
21. CT scans and x-ray have the potential to interfere with some electronic medical devices. Keep pump out of x-ray or scanner range.
22. The RENASYS Negative Pressure Wound Therapy system is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
23. AC mains power can only be removed by disconnecting power cord. Take care in positioning pump to allow access to cord receptacle.
24. If power cord is damaged, wires are frayed or exposed, do not use power cord. Contact your Smith & Nephew representative for a replacement cord.
25. Canisters should be changed at least once a week, whenever there is a change of patient or in the event the canister contents reach maximum volume indication. Do not wait for canister over-capacity alarm activation to change canister.
26. Canisters are single-use devices. Do not reuse.
27. Do not apply SECURA◊ No-sting barrier film wipes directly to open wounds. SECURA No-sting barrier film is flammable. Use in a well ventilated area. Avoid using around flames and sources of ignition. Keep out of reach of children. For external use only.
28. As with all adhesive products, apply and remove dressing carefully from sensitive or fragile skin to avoid blistering and skin stripping, especially after frequent dressing changes. Use of skin sealant may assist with protection of periwound skin.
29. If patient must be disconnected, the ends of the RENASYS Soft Port and canister tubing should be protected using tethered caps to avoid leakage of fluid and cross contamination.
30. RENASYS-F Foam Dressing kit 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.

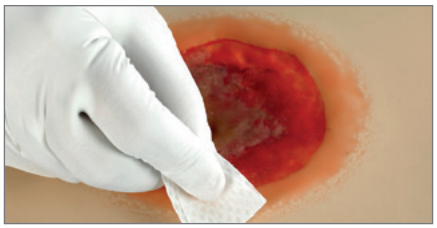
Considerations specific to foam

1. Foam should be cut to fit loosely into wound bed. Never force or tightly pack foam into any areas of the wound to avoid damaging underlying tissue.
2. Never place foam into blind or unexplored tunnels. If a tunnel of known depth presents, cut the foam longer than the tunnel, to ensure direct contact is made with the foam in the primary wound cavity.
3. Do not cut the foam directly over the wound cavity to avoid foam fragments from falling into the wound. Rub the edges of the foam, away from the open wound, to remove loose fragments after cutting.

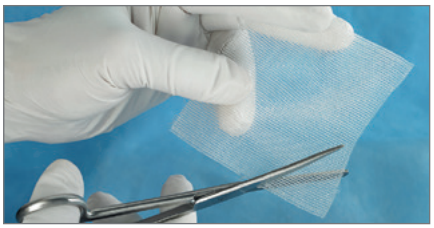
Clean and debride

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

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



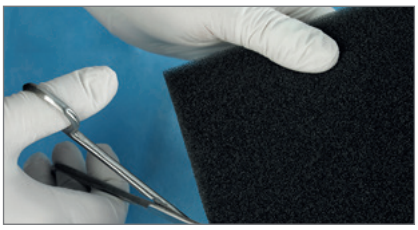
2. If desired, protect the peri-wound skin from exposure to moisture and adhesive through the use of a skin sealant. Allow the skin sealant to dry fully prior to placement of the transparent film.



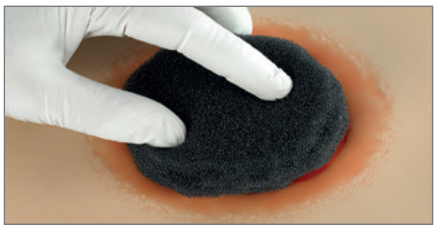
3. If desired, a non-adherent dressing may be applied. Trim a single layer of non-adherent gauze and lay across wound bed.

Dress wound with foam

Review precautions specific to foam before continuing. It is critical that foam is not forced into any wound, or placed within an unexplored tunnel.



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

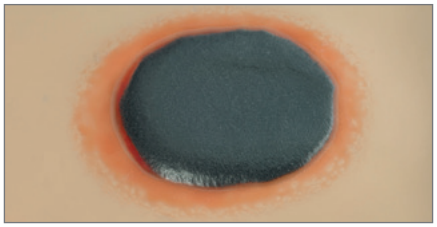


2. Avoid over packing. Foam should completely fill the wound cavity. It may be necessary to stack pieces of foam in deep wounds.

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

Seal the wound

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



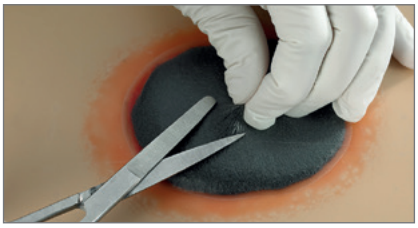
2. Cover wound filler with transparent film, removing remaining adhesive panels to seal, then the top stabilisation panel.

NOTE: Avoid stretching or pulling the transparent film to minimise tension or trauma to the peri-wound skin.

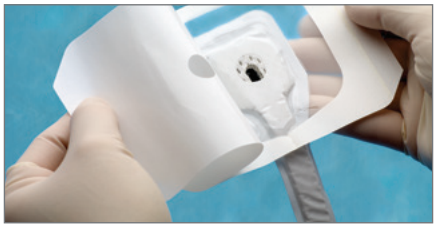
Recommendations:

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

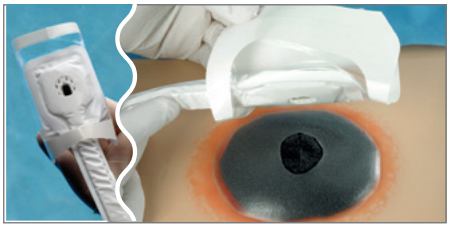
Apply RENASYS◊ Soft Port



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



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



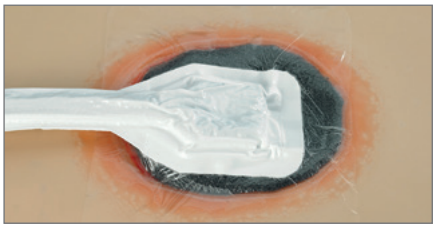
3. Align the Soft Port opening directly over the hole in the transparent film. Use gentle pressure to anchor the Soft Port to the transparent film.

4. Smooth the dressing down while removing the RENASYS Soft Port's top stabilisation frame.

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

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

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



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

RENASYS◇ drain selection and application

The complex nature of wounds which require Negative Pressure Wound Therapy (NPWT) reinforces the need to have a flexible approach to the treatments available. Many patients will present with wounds which may not be optimally treated with the standard RENASYS foam or gauze Soft Port dressing kits.

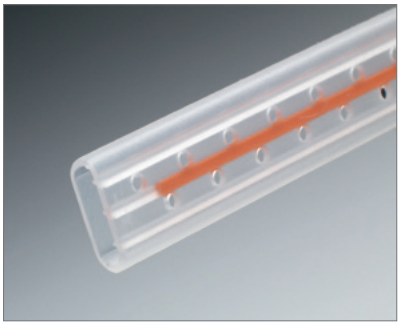
Wounds of complex shapes and depths, challenging anatomical locations and heavy or viscous exudate conditions are more likely to benefit from the use of drain instead of a Soft Port.

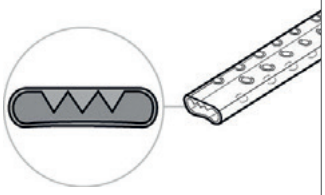
Smith & Nephew provides a variety of stand-alone drain kits and drain accessory kits to support treatment of these wounds. All drains are silicone and feature a radiopaque strip for visualisation under X-ray.

Wounds presenting the following characteristics may benefit from the use of a drain:

- Heavy or viscous drainage
- Explored fistulae
- Sinus wounds involving undermining, tracts and tunnelling

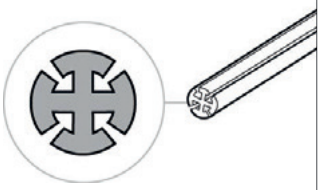
RENASYS drain options are as follows:





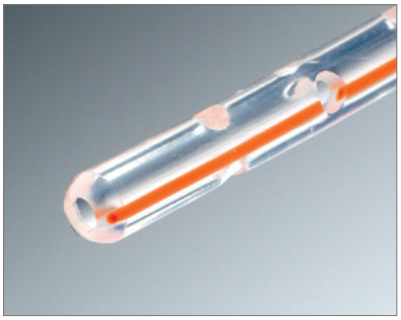
10mm Flat Drain

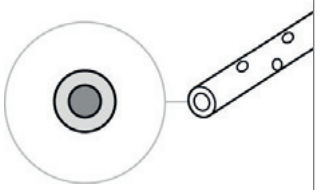
- Multipurpose drain suitable for wide range of wounds, including deep or shallow wounds
- Suitable for heavy or viscous exudate without sediment present
- May be used on weight bearing anatomical areas
- Can be used on wounds with undermining
- Must be positioned to lie flat in the wound - cannot be curled



15Fr Channel Drain

- Non-hollow drain suitable for use in sinus tracts, wounds with tunnelling and/or undermining
- Suitable for low-moderate drainage
- Allows passing of fluid through the four channels of the drain
- Designed with perforations to prevent tissue adherence so can be directly placed without being wrapped in gauze





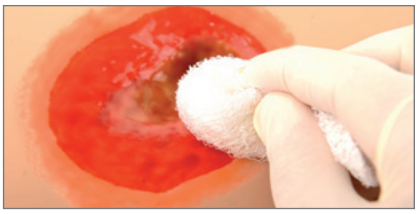
10Fr Round Drain

- Small round drain suitable for small shallow wounds or sinus tracts with narrow openings
- Designed to manage low exudate levels of low viscosity
- Round profile allows for use in undermined areas
- Drain should be wrapped in gauze to prevent to tissue adherence to the drain holes

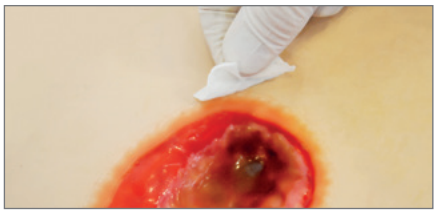
Clean and debride

Refer to the RENASYS® Drain kit Instructions for Use leaflet for further information.

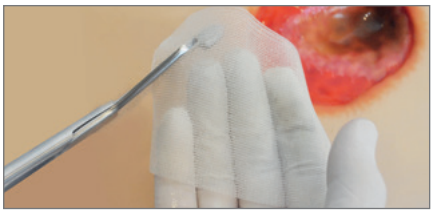
Use clean or aseptic techniques for application, according to your institutional protocol. Thorough wound cleansing should occur with each dressing change.



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



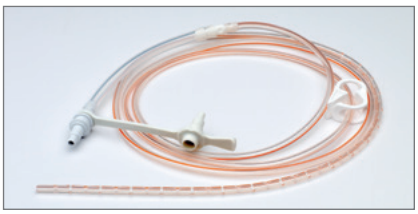
2. If desired, protect the peri-wound skin from exposure to moisture and adhesive through the use of a skin sealant. Allow the skin sealant to dry fully prior to placement of the transparent film.



3. If desired, a non-adherent dressing may be applied. Trim a single layer of non-adherent gauze and lay across wound bed.

NOTE: Skin sealant and wound contact layer are not included as part of the RENASYS Drain Accessory Kits.

Place drain and dress wound with gauze



1. Cut the drain approximately 2.5cm shorter than the base of the wound. Curl the drain if using a channel or round drain. Apply a layer of saline-moistened antimicrobial gauze to the wound bed and position drain on top of gauze.

2. For channel drain, wrap a layer of gauze around drain.
3. 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.

4. Loosen and fluff gauze material prior to placement in the wound cavity. Continue to fill until gauze loosely fills the entire cavity. Avoid over packing the wound.
5. Loosen and fluff gauze material prior to placement in the wound cavity. Continue to fill until gauze loosely fills the entire cavity. Avoid over packing the wound.

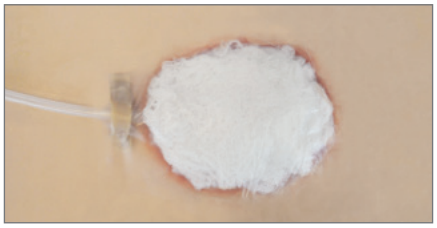
NOTE: If placing channel drain directly into a sinus tract, no gauze is necessary on the portion of the drain in the tract.

WARNING: Drain channels must be contained within the wound bed to achieve a seal.

CAUTION: If using a drain with foam, ensure the drain is placed on top of the foam dressing and not in direct contact with the wound bed.

Seal the wound

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



2. Cover the wound filler with transparent film, removing the remaining adhesive panels to seal, then the top stabilisation panel ensure film covers the strip paste.

3. Create a seal by pinching the strip paste.
4. Secure the drain tubing with waterproof tape.

Recommendations:

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

Initiate therapy

1. Connect the drain to the canister tubing by joining the quick click adapter to the canister connector. An audible click indicates the connection is secure.
2. Activate the RENASYS◊ pump and adjust to the prescribed therapy level.
3. Finished dressings should be firm to the touch and leak-free.
   - Lower levels of vacuum are generally effective and more tolerable.
   - The vacuum level should never be painful. If the patient reports discomfort with the vacuum level, it can be reduced.

Dressing change frequency information can be found in the RENASYS Foam and Gauze Dressing Kits with Soft Port Instructions for Use.

NOTE: The vacuum level is a decision each healthcare provider must make, based on an individual assessment of the particular wound.

RENASYS◇ Dressing Kit options

Wound characteristics	Foam with Soft Port	Gauze with Soft Port	Gauze with flat drain	Gauze with channel drain	Gauze with round drain
Large wound with regular contours	✔		✔		✔
Presence of undermining	✔	✔	✔		✔
Patient has pain on dressing removal		✔	✔		
Weight bearing area	✔				
Heavy exudate levels	✔		✔		✔
Moderate exudate levels	✔	✔	✔		✔
Viscous exudate	✔		✔		✔
Serous exudate	✔	✔	✔		✔
Static chronic wound	✔				✔
Skin grafts	✔	✔	✔		
Sinus wound or wound with narrow opening				✔	
Combination wounds cavity plus sinus (See advanced dressing techniques page 41)	✔		✔		✔

Optimisation of therapy/Enhancing dressing wear time

- Ensure that intact skin is dry prior to applying adhesive dressing.
- Skin sealant such as SECURA◊ NO-STING SKIN-PREP should be routinely used to protect the periwound area. Allow to fully dry prior to applying film dressing.
- If skin in the periwound area is damaged or fragile, a hydrocolloid or adhesive film may be used to protect the area prior to applying the cover transparent film.
- Apply skin sealant such as SECURA NO-STING SKIN-PREP barrier over the edges of transparent film to prevent rolling.
- Apply the RENASYS◊ Adhesive Gel Patch and/or Ostomy Strip Paste to skin irregularities such as abdominal skin folds or cleft at sacrococcygeal junction. This will help to decrease depth of the skin irregularity. See RENASYS Accessory - Gel patch section for more information on application technique.
- Film should extend at least 5cm beyond wound margin and be securely anchored to periwound area to maintain a good seal.
- Overlap the edges of the transparent film by a minimum of 7.5cm/2.95in when using multiple pieces of transparent film.
- If it is necessary to add more foam or gauze to the wound after dressing application, the clinician may create an opening in the film, apply filler, and reseal the dressing as indicated. It is not necessary to restart dressing application.
- It is important to secure the tubing to the patient using extra film or tape to prevent pulling on the dressing which may compromise the dressing seal.
- When a leak is identified or located utilise film dressing to patch the areas without having to replace the dressing.
- If skin irritation is noted underneath the film dressing, discontinue therapy and notify prescribing physician or clinician.
- It is important when applying the film dressing not to pull tightly or stretch the film to avoid trauma to surrounding skin.

Seal the wound

A Smith & Nephew RENASYS® Transparent Film must be used to seal the wound.

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

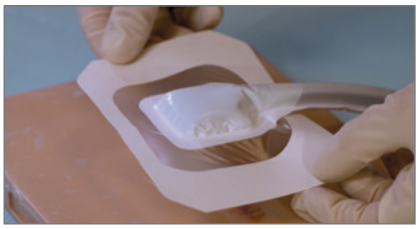
2. While holding the transparent film, expose the side of the adhesive backing by removing a single panel and apply over the wound.

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

Apply RENASYS◇ Soft Port

A Smith & Nephew RENASYS Soft Port must be used to connect the wound to a RENASYS device.

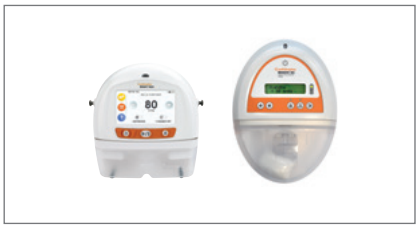
1. Pinch transparent film in the centre over the wound dressing and cut a small hole (larger than 2cm) in the film. Remove any loose film from the wound area and dispose of.



2. Remove the paper handle from the Soft Port dressing and align the port opening directly over the hole in the transparent film. Using gentle pressure, anchor the Soft Port to the transparent film.

3. Smooth the Soft Port dressing down and remove the top paper stabilisation frame.
4. Secure the Soft Port to the patient according to your institutional protocol.

5. Connect the Soft Port to the RENASYS device canister tubing by pushing the quick click connectors together. An audible click indicates the connection is secure.



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

RENASYS◇ ADVANCED DRESSING APPLICATIONS

Y-connector and bridging

RENASYS Y-connector can be used to connect one or two wounds through two RENASYS Soft Ports and/or Drains to a single pump. The RENASYS Y-connector can only be used with the RENASYS TOUCH.

Do not use the Y-connector on two wounds if the RENASYS TOUCH pump display refers to the use of the Y-connector on one wound only.

WARNING: A RENASYS Y-connector should not be used to treat flaps, grafts or open abdomen wounds in a two-wound configuration.

Do not connect an infected and non-infected wound using a Y-connector.

NOTE: RENASYS Y-connector is compatible with RENASYS- G Gauze Dressing Kits with Soft Port, RENASYS-F Foam Dressing Kits with Soft Port, RENASYS AB Abdominal Dressing Kit with Soft Port and all RENASYS Drain kits.

Precautions

1. As a condition of use, the RENASYS◇ NPWT system should only be used by qualified and authorised personnel. The user must have the necessary knowledge of the specific medical application for which the RENASYS Y-connector is being used.
2. The dressing seal may be lost or pooling may occur, without alarm activation, when an occlusion forms on the wound side of the dressing. Viscous, purulent or serosanguinous drainage may contribute to occlusion of the dressing. Regular monitoring of the pump and dressing is required to ensure full delivery of therapy and exudate removal. Ensure the wound dressing is free of air leaks, fully compressed and firm to the touch whenever therapy is active.
3. For RENASYS TOUCH, do not use the Y–connector on two wounds if the pump display refers to the use of the Y–connector on one wound only.
4. When bathing or showering the patient must disconnect from the RENASYS Y–connector leaving it on the pump. Use the connector caps on the Soft Port and Y–connector to avoid leakage of wound fluid. Ensure the aeration disc located near the orange quick click connector is free of moisture before reactivation of therapy to ensure proper alarm functionality and prevent interruption in therapy.
5. RENASYS Y–connector should only be used with Smith & Nephew authorised components. Use of the Y-connector with other products has not been proven safe and effective for use with RENASYS pump.
6. NPWT should remain on for duration of treatment. The length of time a patient may be disconnected from the pump is a clinical decision based on individual characteristics of the patient and wound. Factors to consider include location of wound, volume of drainage, integrity of dressing seal, assessment of bacterial burden and patient's risk of infection.
7. RENASYS Y-connector 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.
8. Avoid using a RENASYS Y-connector to connect wounds that would be optimally treated using differing pressure settings.
9. The same type of dressing kit should be used when treating two wounds using the RENASYS Y-connector.
10. Do not use a Y-connector with breached or damaged packaging.
11. Patients and caregivers should not attempt to troubleshoot any issue themselves. They should attempt to contact their Healthcare Professional for assistance. This instruction for use 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 instruction for use and all applicable labelling.

Warnings

1. The pump alarm functionality is reduced when using the Y-connector. Monitor the RENASYS pump and dressing as follows:
   - Two wound configuration at least every 24 hours
   - One wound configuration at least every 72 hours
2. When a Y-connector is used in conjunction with RENASYS AB Abdominal dressing kit, the Y-connector should only be in a one-wound configuration.
3. Monitor the patient more frequently when treating infected wounds. If there are any signs of systemic infection or advancing infections in the area around the wound, contact the treating clinician immediately.
4. Care should be taken to ensure that the Y-connector does not lie in a position where it could cause pressure damage to the patient.
5. Do not use the Y-connector to:
   a. Treat more than two wounds
   b. Connect multiple Y-connectors to a single pump
   c. Connect an infected and non-infected wound
   d. Connect two patients to a single pump
   e. Connect flaps and or grafts in a two wound configuration

Advanced dressing techniques

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

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

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

Managing multiple wounds

- If both wounds must be monitored, consider a bridging technique using a single Soft Port instead of a Y-connector. Also consider using two devices.
- When treating separate wounds, or utilising two devices, the clinician should regularly check the wound being treated with the drain or Soft Port to ensure the dressing is compressed.

Using a Y-connector

Review all RENASYS◇ NPWT system safety information prior to beginning wound preparation. Always consult the instructions for use provided with the RENASYS TOUCH pump and dressing kit in addition to the instructions provided in this leaflet for information on application, precautions and warnings.

1. Prepare the wound site in accordance with the instructions provided in the leaflet for the relevant RENASYS dressing kit.
2. Prepare the pump for use in accordance with the setup instructions provided in the relevant pump manual. Do not initiate therapy.
3. Connect the RENASYS Y-connector main channel to the canister tubing by pushing the orange quick click connectors together. An audible click indicates the connection is secure.
4. Connect the Soft Ports and/or drains to the RENASYS Y-connector branches. An audible click will indicate that the connection is secure.
5. Activate the RENASYS pump ensuring that it is operating at the prescribed therapy level. The recommended therapeutic pressure range is 80mmHg to 120mmHg when using a Y-connector. The pressure setting must be determined by a healthcare professional based on an individual assessment of the wound.

6. It is recommended to leave the pump connected to the mains power or check the battery status of the pump frequently when using a RENASYS Y-connector.
7. The use of two soft ports in conjunction with a RENASYS Y–connector and RENASYS GO is recommended when the pump's pressure setting is set below 120 mmHg. If a pressure setting above 120mmHg is required, a RENASYS TOUCH should be used. If the RENASYS Y-connector is not appropriate, use two separate pumps to handle the additional demand for delivering negative pressure to both wounds.
8. Confirm that the RENASYS pump has been activated in accordance with relevant pump manual.
9. Check that NPWT is being delivered to the wound site(s). Confirm that the dressing has a raisin–like appearance and is firm to the touch.

RENASYS Y-connector changes and temporary detachment

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

RENASYS Y-connector removal/disposal

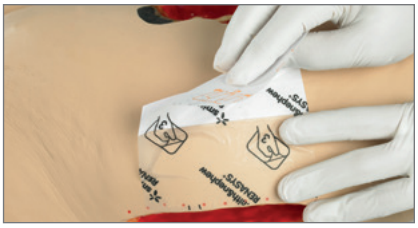
12. Turn off the RENASYS pump.
13. Disconnect the Y-connector from the Soft Port or drain adapter by applying gentle pressure to the quick click connector and then pulling the connectors apart. Use the caps to cover the quick click connector on the Soft Port/Drain and the Y-connector.

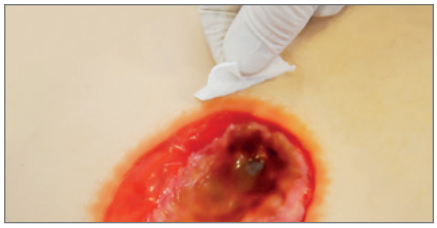
Disconnecting the Quick Click Connectors and using the caps to avoid fluid leak.

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

Bridging – Managing multiple wounds with the RENASYS◇-G Gauze Dressing Kit or the RENASYS-F Foam Dressing Kit with 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.





1. Protect intact skin in area under bridge and between the wounds with transparent film.

   Consider bridging two wounds together using wound filler for wounds separated by a distance less than 25cm. If the wounds are greater than 25cm consider using a Y-connector.

   Cut additional foam or gauze and place on top of transparent film to form the bridge.

2. Complete NPWT dressing application technique for the RENASYS-F Foam or RENASYS-G Gauze dressings – covering both the wound and bridge with transparent film.
3. Initiate negative pressure.

Bridging away from the wound

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

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

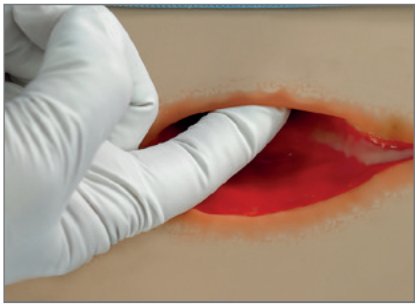
- When using a bridging technique, choose a location where the bridge is least likely to be weight bearing. This will support the bridge remaining open to optimise transfer of fluid and vacuum.

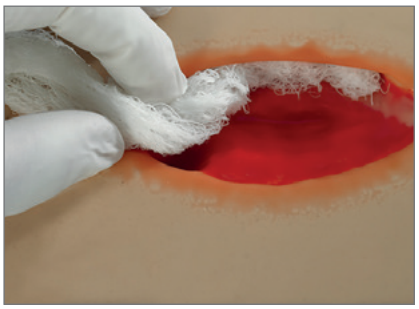
Undermining and/or tunnelling

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:





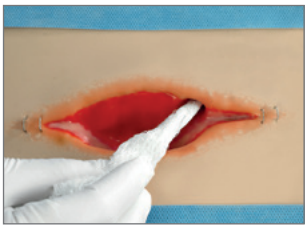
- Utilising saline moistened gauze, loosely fill the undermined areas and any dead space of the wound.
- Once the undermined areas have been filled with moistened gauze, gauze or foam may be used to fill the remainder of the wound making sure that all areas of the wound are in contact with wound filler.
- Cover with transparent film as indicated.
- Continue with RENASYS◇ dressing application technique, seal the wound.

Tunnelling or sinus tracts

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

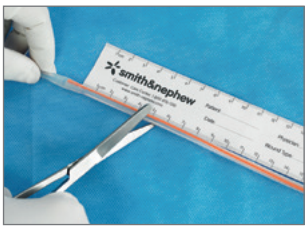
Ways to address tunnels or sinus tracts

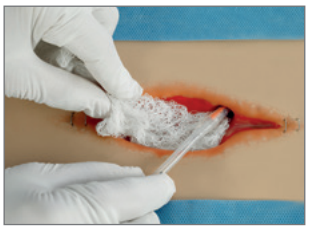
Option 1

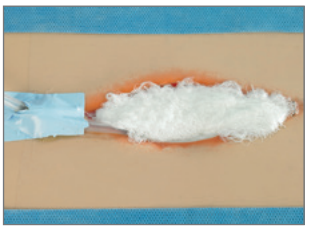


- Fill tunnels or sinus tract with moistened gauze or sterile packing strips, pulling out/back 0.5 to 1 cm to allow for healing distal to proximal.
- Make sure the tunnel filler material is visible and accessible in the wound bed to assure complete removal upon dressing change.
- Filler material in tunnels may contract when compressed, it is important to leave a tail to facilitate removal.
- Continue with RENASYS◇ dressing application technique utilising 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 section for further channel drain information.
- Measure tunnel by inserting the channel drain to base of tunnel.
- Pull back on the drain by 0.5-1cm to prevent pressure and allow for healing at distal end of tunnel.
- The portion of the channel drain in the tunnel/sinus tract is left unwrapped and free of wound filler material.
- Wrap the remainder of the channel drain with saline moistened gauze assuring that the drain hub and junction is in the middle of the wound and at least one layer of moistened gauze is between the channel drain and wound bed.
- Fill any dead space or remainder of the wound with additional saline moistened gauze or foam filler.
- Continue with RENASYS dressing application technique seal the wound.

Skin grafts

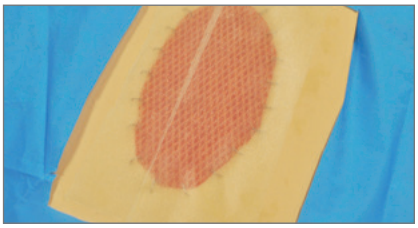
Treatment goal

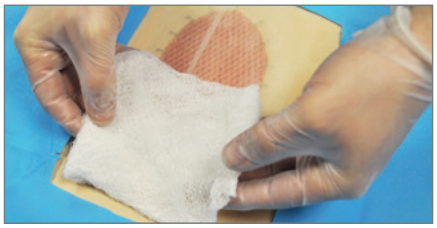
- Bolster the graft in place to prevent shearing and minimise movement of the graft.
- Eliminate accumulation of wound fluid beneath the graft that could lead to the graft lifting and impact upon graft take.

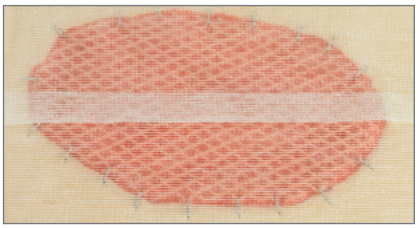
Suggested pressure setting and dressing change frequency

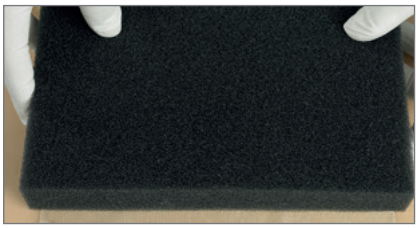
- Pressure setting recommendation is -40 to -120mmHg in continuous mode.
- Ultimately, the pressure setting is a decision to be determined by the physician/clinician. Generally, lower pressure setting are utilised (-60 to -80mmHg) for skin grafts.
- Foam dressings should be changed every 48–72 hours after the initial application of therapy. If no leak is present and the patient is comfortable, dressing changes should occur no less than 3 times per week.
- Gauze dressings should be changed 48 hours after the initial application of therapy. If no leak is present and the patient is comfortable, dressing changes should occur 2-3 times per week.
- Exudate level should decrease after the first 24-48 hours.
- Duration of therapy is also a physician/clinician decision (generally 3-10 days).
- Negative Pressure Wound Therapy (NPWT) should remain on continuously to ensure the graft remains bolstered at all times.
- When utilising foam dressing kit it is important to apply a wound contact layer between the graft and the foam to avoid adherence to the foam.[5]

Dressing application of skin graft with RENASYS◇ Soft Port









1. Cover the entire graft with a non-adherent layer and extend the contact layer at least 2.54cm past the suture/staple line.
2. Cut foam or gauze to the size and shape of the contact layer, not to extend past the wound contact layer or come in contact with healthy skin to avoid damage to surrounding tissue.
3. Place cut foam or gauze on top of the contact layer.

Continue with RENASYS dressing application technique seal the wound (See dressing application, gauze page 35 or foam page 40).

Abscess dressing technique: RENASYS◇ channel drain

- This technique can be used if the entrance site to the abscess cavity is the same size or only slightly larger than the channel drain diameter (10Fr).
- After cleaning the wound, pat peri-wound skin dry and apply a skin sealant such as SECURA◇ NO-STING SKIN-PREP.
- Protect peri-wound skin by applying hydrocolloid or other protective dressing.
- Cut the channel drain to length of the abscess minus 0.5-1 cm to allow for contraction.
- Insert drain into abscess ensuring the 'hub' or the suction source of the channel drain is secure inside the wound bed.
- Secure drain and follow RENASYS drain application technique.
- Cover entire area, including strip paste, with transparent dressing.

NOTE: Further information on drains can be located on page 37.

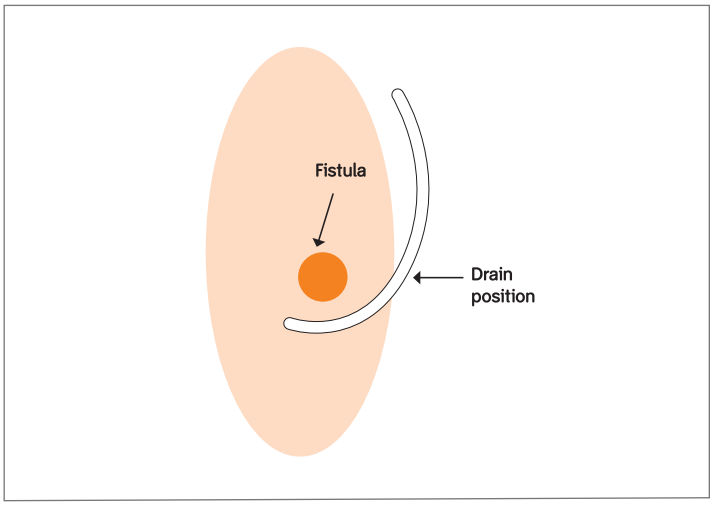
Fistula management - Isolation technique

1. Clean the wound according to facility protocol and isolate the fistula by wrapping a non-adherent gauze or barrier around the base of the fistula to protect from drainage.
2. Utilise gauze or other absorptive material at the opening of the fistula to manage drainage while dressing the wound. May also use wall suction with catheter to manage effluent during dressing application.
3. Cover the base of the wound with non-adherent layer if necessary.
4. Cut and fit the foam or gauze dressing into the wound. Important: Do not place foam or gauze wound fillers over the opening of the fistula.
5. Apply film dressing over the wound and attach Soft Port dressing. (See dressing application steps page 30/36). Initiate Negative Pressure Wound Therapy (NPWT) to ensure that a seal is achieved.
6. Once seal has been achieved, turn therapy off, and gently cut a hole in the dressing directly over the covered mouth of the fistula to expose mouth.
7. Remove gauze covering from mouth of fistula and expose the fistula in order to attach an ostomy appliance or fluid collection device of choice.
8. Initiate NPWT and apply the collection device to isolated fistula ensuring a good seal.
9. Use continuous therapy and monitor canister and dressing frequently.

NOTE: It is important that the mouth of the fistula be visualised in order to utilise the isolation technique.

Types of fistulas

- 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.



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

- Fistulas may also be described by amount of output:
  - High output – 500ml or more/24 hours
  - Moderate output – 200-500ml/24 hours
  - Low output – less than 200ml/24 hours
- The wound surrounding the fistula opening should respond as any other wound on NPWT by displaying decreased size, decreased drainage, and increase in granulation tissue. The fistula opening will likely require surgical intervention or pouching depending on the maturation of the fistula.

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

RENASYS◇ Adhesive Gel Patch

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

The wear time is up to 72 hours.

Application tips

- The RENASYS Adhesive Gel Patch is intended to be used on intact skin. It is primarily used to improve seals and avoid leaks.
- Used under the RENASYS Transparent Film, the gel patch can be cut and placed around the periwound area prior to sealing with the RENASYS Transparent Film.
- It may be easier to cut or shape the RENASYS Gel Patch prior to removing the adhesive backing.
- When using gloves, remove one side of the adhesive backing and apply to the skin. Remove the remaining panel once placed.
- The gel patch has absorbent properties, which means it 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.

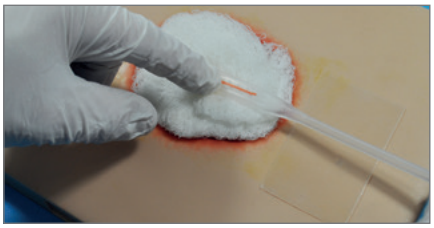
Product application areas

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

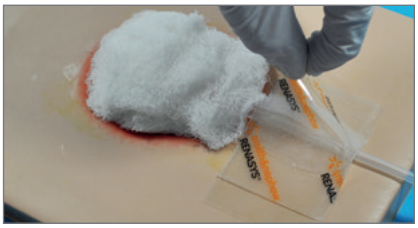
Creating a seal around drain tubing or to lift drain off skin

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

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



3. Remove the remaining backing and apply tubing.

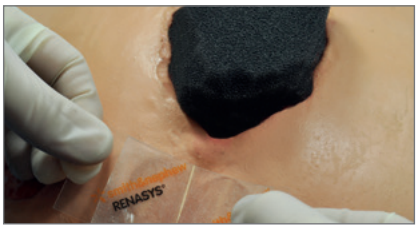


4. Apply another strip using the same technique over the top of the tubing.

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

Creating a seal in challenging anatomical areas

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

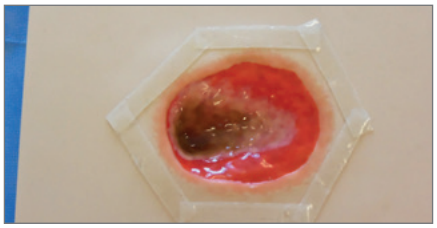


2. Remove the backing on one side only and apply to skin with gentle pressure. Ensure the fold is addressed first.

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

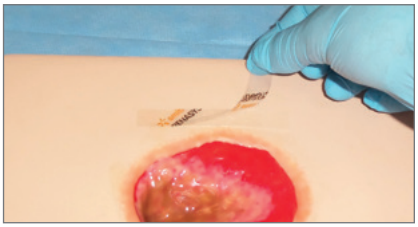
Creating a seal around wound margins.

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

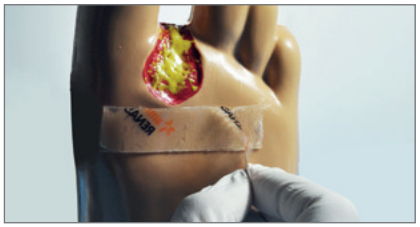


2. Continue to apply gel strips around wound margins ensuring that the strips overlap to create a good seal. Continue with normal dressing application.

Creating a seal in challenging areas of the foot

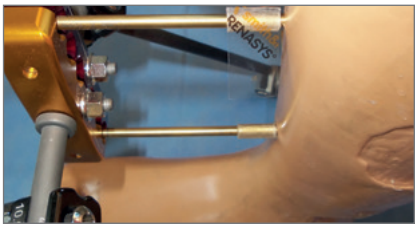


1. Cut the gel patch into strips in a direction with backing removal ends accessible.

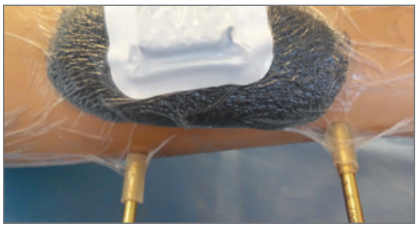


2. Remove the backing on one side only and apply to skin with gentle pressure. Remove the backing. Apply transparent film over the foam or gauze interface and the gel patch to create a seal and finish the dressing.

Creating a seal around external fixation pins



1. 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.



2. 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.

Protecting vessels and organs

Directions:

Caution should be taken to ensure that all organs and/or vessels are completely covered prior to initiating NPWT. It is the responsibility of the treating clinician to determine the appropriate natural tissue and/or non-adherent wound contact layer to be utilised to protect and prevent organs or vessels from having direct contact with NPWT.

When using a non-adherent wound contact layer, the treating clinician should consider utilising multiple layers and securing to prevent movement during NPWT.

WARNING: The use of Negative Pressure Wound Therapy (NPWT) is contraindicated and should never be placed in direct contact with exposed vessels and organs

RENASYS◇ ABDOMINAL KIT

Description and indications for use

Introduction

In the past decade there has been increasing evidence to suggest that using Temporary Abdominal Closure (TAC) techniques can help to reduce mortality in patients with Intra-Abdominal Hypertension (IAH) and help prevent development of Abdominal Compartment Syndrome (ACS).[32] Negative pressure dressings have been used for a number of years to help facilitate TAC and have been proven to be a reliable treatment due to excellent clinical benefits in appropriate circumstances.

The primary aim of Temporary Abdominal Closure is to reduce pressure within the abdominal cavity. Reducing the Intra-Abdominal Pressure (IAP), can prevent or reduce the risk of the patient developing Abdominal Compartment Syndrome.[33]

Reducing the pressure in the abdominal cavity also reduces the likelihood of respiratory, renal and cardiac complications.[33]

RENASYS◇ ABDOMINAL KIT

The RENASYS◇ AB Abdominal Dressing Kit used in conjunction with the RENASYS EZ PLUS/EZ MAX system devices help facilitate temporary abdominal closure using Negative Pressure Wound Therapy.[34]

RENASYS TOUCH can also be used in conjunction with the RENASYS AB Abdominal Dressing Kit.

Indications for use

The RENASYS AB Abdominal Dressing Kit with Soft Port is intended for use in conjunction with RENASYS TOUCH, RENASYS EZ PLUS and RENASYS EZ MAX devices and canisters as a complete Negative Pressure Wound Therapy (NPWT) System for managing open abdominal wounds with NPWT.

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

Contraindications

The use of RENASYS AB is contraindicated:

- For non-enteric, unexplored fistulae.
- For untreated osteomyelitis.
- For malignancy in the wound (with exception of palliative care to enhance quality of life).
- When vital organs and structures are not covered with the Organ Protection Layer (OPL).
- For presence of necrotic tissue with eschar.
- For use in patients with on-going or high potential for haemorrhage and/or enteric leak.

Foam should never be placed in contact with exposed bowel, arteries, veins, organs, or nerves.

Utilise the OPL at all times when using the RENASYS AB with the RENASYS NPWT System.

Warnings

1. Haemostasis must be achieved prior to dressing application. Carefully monitor patients undergoing treatment with RENASYS AB for signs of sudden or increased bleeding. If such signs are observed, immediately discontinue therapy, take appropriate measures to control the bleeding, and contact the treating clinician.
2. Patients suffering from difficult haemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using haemostatic products that, if disrupted, may increase risk of bleeding.
3. Do not use directly 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 closer under the action of negative pressure.
4. NPWT has not been studied on paediatric patients. Patient size and weight should be considered when prescribing the device.
5. 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. Over-packing may interfere with distribution of NPWT evenly across the wound. This may decrease the ability of the wound to properly contract and permit fluid to remain in the wound.
6. In the event defibrillation is required, disconnect pump from the wound dressing prior to defibrillation.
7. The pump is not MRI compatible. Do not bring device into MRI suite. Prior to entering MRI suite, disconnect pump from dressing. The dressing can remain intact on patient.
8. Pump is unsuitable for use in areas where there is danger of explosion (e.g. hyperbaric oxygen unit).
9. When operating, transporting or disposing of pump and accessories, there is risk of infectious liquids being aspirated or contamination of system assembly through incorrect use. Universal precautions should be observed whenever working with potentially contaminated components or equipment.
10. Pump and canister are provided non-sterile and should not be placed within a sterile field.

Precautions

1. More frequent pump and wound dressing monitoring, should be taken for patients who are or may be:
   - Suffering from infected blood vessels
   - Receiving anticoagulant therapy or platelet aggregation inhibitors, in addition to patients with intrinsic coagulation problems such as low platelet counts
   - Actively bleeding or have friable blood vessels or organs
   - Suffering from difficult wound haemostasis
   - Untreated for malnutrition
   - Noncompliant or combative
   - Suffering from wounds in close proximity to blood vessels or delicate fascia

When monitoring patients for delivery of therapy, ensure wound dressing is free of air leaks, fully compressed and firm to the touch. Ensure that pressure indicated on pressure gauge reflects set pressure on pressure selector knob.

2. As a condition of use, pump should only be used by qualified and authorised personnel. User must have necessary knowledge of the specific medical application for which NPWT is being used.
3. The dressing seal may be lost or pooling may occur, without alarm activation, when an occlusion forms on the wound side of the dressing. Viscous, purulent or serosanguineous drainage may contribute to occlusion of the dressing. Regular monitoring of pump and dressing is required to ensure full delivery of therapy and exudate/transudate removal. Ensure the wound dressing is free of air leaks, fully compressed and firm to the touch whenever therapy is active.
4. For patients with high risk of bleeding use 250ml or 300ml canister. Ensure the 250ml canister viewing window is checked frequently for signs of bleeding, as the canister holder obscures the viewing window.
5. To minimise risk of bradycardia, do not place RENASYS® AB Kit System in proximity to the vagus nerve.
6. In the event a patient with spinal cord injury experiences autonomic dysreflexia, discontinue use of NPWT and immediately seek medical assistance.
7. Monitor patient for any signs of local or systemic infection. infected wounds may require more frequent dressing changes. If there are any signs of systemic infection or advancing infection at wound area, contact treating clinician immediately.
8. If multiple pieces of foam are needed to fill the wound profile, count and record how many pieces are present to ensure all pieces are removed at a dressing change to minimise the risk of retention and possible infection.
9. NPWT should remain on for duration of treatment. The length of time a patient may be disconnected from device is a clinical decision based on individual characteristics of patient and wound. Factors to consider include location of wound, volume of drainage, integrity of dressing seal, assessment of bacterial burden and patient's risk of infection.
10. Do not use a dressing kit with breached or damaged packaging.
11. Use of NPWT presents risk of tissue in-growth. Tissue in-growth may be reduced by using the provided wound contact layer or increasing the frequency of dressing changes.
12. Maintain regular monitoring of pump and wound site during therapy to ensure therapeutic treatment and patient comfort.
13. RENASYS AB is only to be used with Smith & Nephew authorised components.
14. Ensure canister tubing and RENASYS Soft Port are installed completely and without any kinks to avoid leaks or blockages in vacuum circuit. Position pump and tubing appropriately to avoid risk of a trip hazard. Pump and system tubing should be positioned level with or below wound to ensure optimisation of therapy and prevent therapy interruption.
15. Sponge bathing is allowable with the kit in place so as long the aeration disc remains free of moisture.
16. If any liquids penetrate pump, discontinue use and return to your Smith & Nephew authorised provider for service.
17. CT scans and x-ray have the potential to interfere with some electronic medical devices. Keep device out of x-ray or scanner range.

18. The RENASYS◇ Negative Pressure Wound Therapy system is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
19. Ensure pump is placed on a stable level surface. When placed on an uneven surface, pump can become unbalanced as exudate fills canister.
20. AC mains power can only be removed by disconnecting power cord. Take care in positioning pump to allow access to cord receptacle.
21. If power cord is damaged, wires are frayed or exposed, do not use power cord. Contact your Smith & Nephew representative for a replacement cord.
22. Canisters should be changed at least once a week, whenever there is a change of patient or in the event the canister contents reach maximum volume indication (300ml or 800ml fill line). Do not wait for canister over-capacity alarm activation to change canister.
23. The in-line bacterial overflow guard is designed for single patient use and is provided as part of the single-use canister. The guard is replaced each time canister is changed. Check guard for any changes in colour, liquid in guard or poor vacuum performance. Replace canister, inclusive of guard, if any of these occur.
24. Canisters are single-use devices. Do not reuse.
25. Do not apply SECURA◇ No-sting barrier film wipes directly to open wounds. SECURA No-sting barrier film is flammable. Use in a well ventilated area. Avoid using around flames and sources of ignition. Keep out of reach of children. For external use only.
26. As with all adhesive products, apply and remove dressing carefully from sensitive or fragile skin to avoid blistering and skin stripping, especially after frequent dressing changes. Use of skin sealant may assist with protection of periwound skin.
27. If patient must be disconnected, the ends of the RENASYS Soft Port and canister tubing should be protected using tethered caps to avoid leakage of fluid and cross contamination.
28. RENASYS AB Abdominal dressing kit 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.

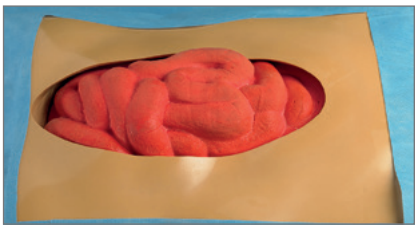
Precautions specific to RENASYS◇ AB

1. Surgical intervention with RENASYS AB should only be undertaken as part of a holistic medical management strategy.
2. Frequent, standardised measurements of 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.
3. 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.
4. Use of the OPL is necessary to protect exposed organs from the foam and extraperitoneal tissues to which adhesion may form. Preventing adhesions or obstructions that may otherwise form during open abdominal wound management is a critical parameter in achieving timely primary facial closure and reducing the chance of fistula development. The OPL must completely cover all exposed viscera, prior to application of wound filler and subsequent activation of the NPWT system.
5. Use caution when utilising RENASYS AB with patients suffering from obstruction in the small or large intestine, 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).
6. Patients with vascular or intestinal anastomosis (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.
7. During the course of treatment, the RENASYS AB dressing and NPWT system will remove third space fluid from the abdominal compartment. Large volumes of fluid can be collected during the course of treatment. The volume and appearance of the fluid in both canister and canister tubing should be checked and recorded frequently while patient is receiving therapy. The canister should be replaced when contents reach maximum volume indication (300ml or 800ml fill line). Viscous exudates increase the risk of blockage in the system; monitor closely.
8. The fluid level in the canister may be used as an approximate guide when considering the necessity of fluid replacement. Planning for fluid replacement should be a clinical consideration in all patients undergoing therapy with RENASYS AB.
9. Protection of the peri-wound skin area from moisture and adhesive irritation may be accomplished through the use of a skin-sealant. Allow the skin-sealant to dry fully prior to placement of the transparent film. 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.
10. The lowest recommended therapy pressure for using RENASYS AB with RENASYS TOUCH device is -80mmHg.
11. While using RENASYS AB, apply universal precautions according to your institution's protocols, to minimise the risk of contact with any blood-borne pathogens.

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

Dressing application technique

Preparation of open abdominal wound

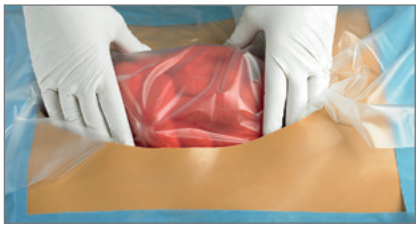


1. Eliminate any sharp edges or bone fragments from wound area (refer to PRECAUTIONS SECTION).
2. Ensure any areas of necrosis are appropriately debrided.
3. Irrigate abdominal wound as needed.
4. Clean and dry the periwound area.

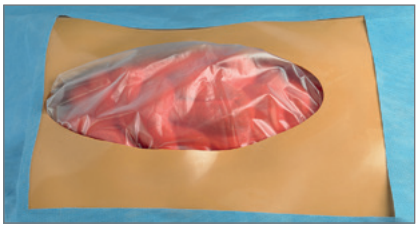
WARNING: Review all RENASYS◇ Negative Pressure Wound Therapy (NPWT) System safety information prior to beginning Wound Preparation. Ensure that sufficient haemostasis has been achieved prior to applying the RENASYS AB dressing (refer to WARNINGS SECTION).

Organ Protection Layer (OPL) Application

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



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



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

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

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

Perforated foam application

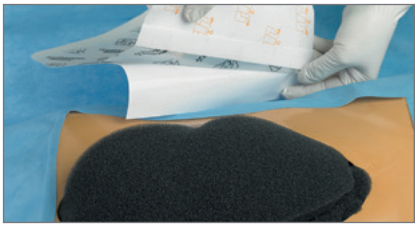
1. Size the provided foam to the desired proportions along pre-scored perforations. Cutting the wound filler may be performed if desired. Do not cut the foam wound filler directly over the wound bed to avoid foam fragments from falling into the wound. Rub the edges of any cut foam, away from wound, to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

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

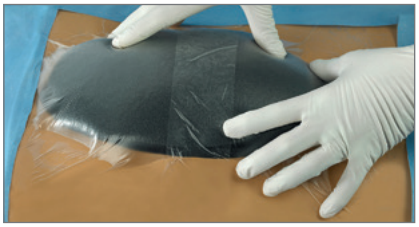
NOTE: Do not allow foam to contact intact skin without use of appropriate barrier, such as transparent film or a hydrocolloid. It may be necessary to stack pieces of foam in deep wounds depending on the wound profile. If multiple pieces of foam are needed, count and record the number of foam pieces used.

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

Transparent film application



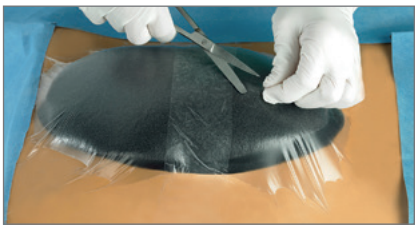
1. While holding the transparent film, expose one side of the adhesive backing by removing a single panel and apply it to the foam.



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

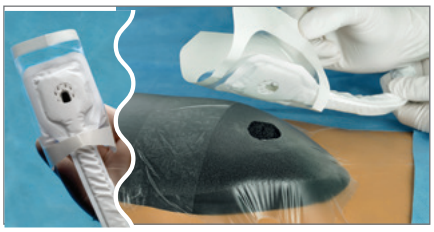
NOTE: Overlap the edges of the transparent film by a minimum of 7.5cm when using multiple pieces of transparent film. Avoid stretching or pulling the transparent film to minimise tension or trauma to the peri-wound skin.

Apply RENASYS◇ Soft Port



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

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



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

4. Smooth the dressing down while removing the RENASYS Soft Port's top stabilisation frame.

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

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

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

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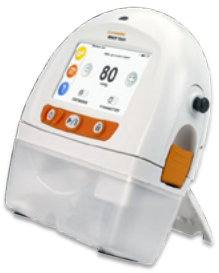
RENASYS TOUCH
Competency performance criteria

smith&nephew
RENASYS◇ TOUCH
Negative Pressure Wound Therapy



Evaluator:_____ Date:_____

Name (person being tested): _____

RENASYS TOUCH functionality

Basic functionality:

1. **Turn device On/Off** ☐
2. **Lock/Unlock the home screen** (lock will automatically initiate after 5 minutes and screen will darken, and, in the event of an alarm, the screen will automatically unlock and light up) ☐

Starting therapy:

3. **Switch between Continuous and Intermittent therapy modes** ☐

Continuous therapy:

4. **Ensure device is in Continuous mode and change therapy settings to -25mmHg and start therapy.** ☐

Leak check

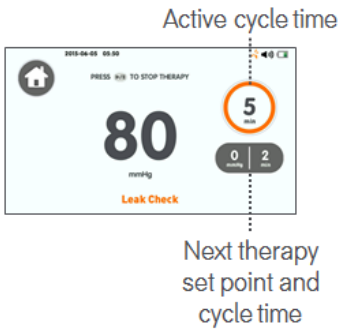
Ensure green light is displayed on top of the device

Therapy indicator: Check that Smith & Nephew energy burst is orange and rotating

Variable Intermittent therapy:

5. **Switch device into Intermittent mode and change the therapy settings to High 120mmHg 10 minutes and Low setting to -25mmHg for 5 minutes. Check that Leak check is working, green light is displayed on top of the device, and Smith & Nephew energy burst is orange and rotating.** ☐

Therapy display: This will show you if therapy is in the High or Low cycle and what time is left on that cycle.



Variable Intermittent options:

High -25,40,50,60,70,80,90,100,120,140,160,180,200

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

Cycle times:

High cycle time :3,5,8,10 minutes

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

Settings:

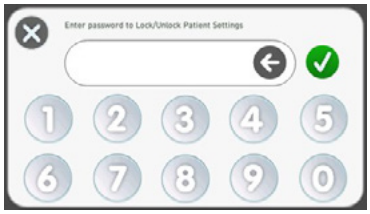
6. **Access the settings menu**

7. **Alarm volume: Change Alarm setting from High to Low**
8. **Compression rate: Change from High setting to Low setting**

9. **Change mode: Change device from Clinician mode to Patient mode (3141)**

   Note restricted features in Patient mode:

   - Therapy mode
   - Therapy settings
   - Y-Connect feature
   - Restore presets



10. **Locate the following features:**

    Language

    Time zone

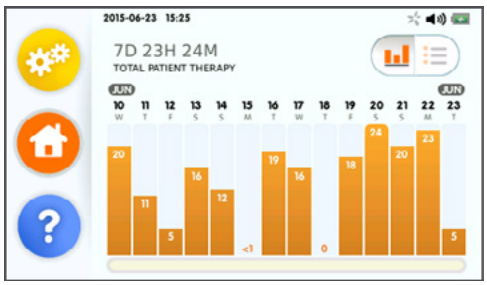
    Restore presets

    Device information – Serial number, percent battery remaining, device lifetime therapy and maintenance due date

Log

11. **Access Patient log screen** – details the total duration of patient therapy and day by day hourly usage

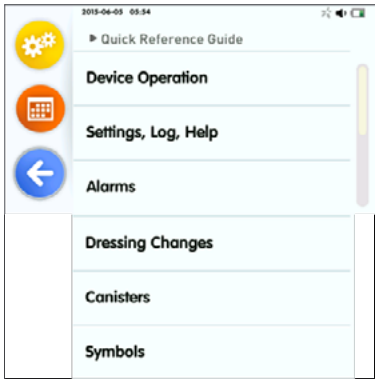
12. **Access pump activity history screen** – details total patient pump activity and displays a history of pump events by date and time, including therapy settings, alarms and device status



Help: The Help section provides guidance on device functions and operation, troubleshooting assistance, Smith & Nephew contact information, and licensing details

13. Access the Help menu

14. Access the troubleshooting guide for the blockage alarm, read information and return to the help menu
15. Access the Quick Reference Guide
16. Locate information about the therapy log
17. Locate information about the Leak alarm
18. Locate information about changing the RENASYS® TOUCH canisters



What do the following symbols indicate:

19. 

20. 

21. 

22. 

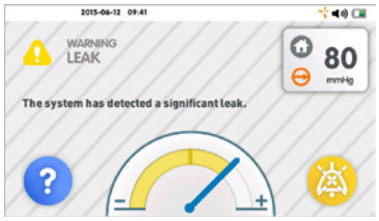
Dressing application

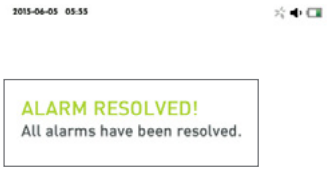
1. Complete a dressing application on supplied wound model, attach canister to device and connect canister to RENASYS° Soft Port. Start therapy on Continuous at -80mmHg ☐

Alarms functionality and troubleshooting:

Leak alarm:

2. Introduce a leak into the dressing to activate the Leak alarm so Leak alarm screen is displayed ☐
3. Navigate away from the alarm screen to the troubleshooting guide ☐
4. Return to the alarm screen from the troubleshooting guide (using alarm button) ☐
5. Use the Flow meter to assist in identifying the location of the leak. Resolve the leak and ensure therapy is successfully delivered ☐





Blockage alarm:

6. Disconnect canister tubing from the dressing and kink tubing to introduce a Blockage alarm so Blockage alarm screen is displayed ☐
7. Navigate away from the Alarm screen to the Blockage alarm troubleshooting guide ☐
8. Return to the Alarm screen from the troubleshooting guide (using Alarm button) ☐
9. Unkink the tubing and reattach the canister tubing to the wound model and ensure alarm is resolved and therapy is being successfully delivered ☐

RENASYS◇ APPENDIX

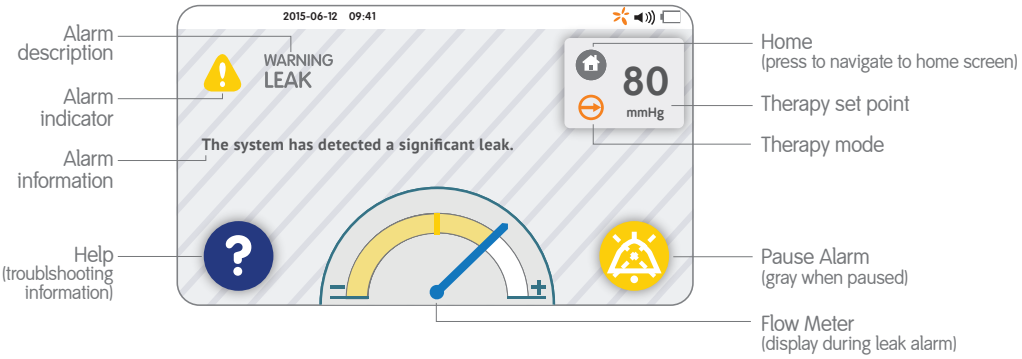
RENASYS TOUCH troubleshooting

The RENASYS TOUCH device is equipped with alarms to indicate an error in the system. All alarms are determined to be “Low Priority” and require user awareness (IEC 60601-1 and IEC 60601-1-8). In the event of an alarm, an audible tone sounds, an alarm screen will display and the status indicator illuminates yellow.
The device stops delivering therapy in the occurrence of an Over Vacuum, High Vacuum, unattended Critical Battery, unattended Battery Failed or Device Failed alarm.

CAUTION: Alarms are not intended to replace physical inspection and monitoring of system operation by health care providers. There are scenarios that may occur during therapy that can impact alarm functionality. Therefore, it is important that the patient, device and wound dressing are monitored regularly to ensure therapy is being delivered.

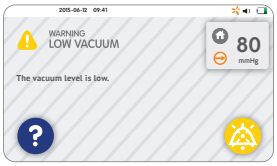
Some alarms allow the audible alarm to be paused for approximately 2 minutes. The Low Battery alarm allows the audible alarm to be paused for 15 minutes. If the cause of the alarm is not resolved within this time the alarm will recommence. If the audible alarm has been paused and a new alarm state occurs, the audible alarm sounds, and the touchscreen will display the new alarm. When multiple alarm states are present, the device will alternate between alarm screens every 5 seconds.

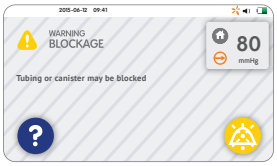
Alarm screen (Leak alarm shown)



NOTE: Alarm screen icons and features display only when applicable

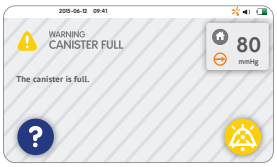
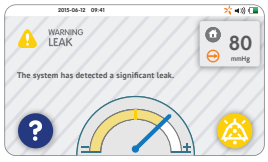
IMPORTANT: This guide is intended as a technical troubleshooting guide only. It does not constitute medical advice and appropriate medical attention must always be sought in the event that a clinical issue is suspected.

Alarm status with display screen	Cause	Remedy
Low vacuum alarm • Status indicator illuminates yellow. • Audible alarm sounds every 20 seconds. • Audible alarm may be paused for approximately 2 minutes by pressing the Pause Alarm icon on the screen. 	The vacuum level is lower than the therapy set point by >15mmHg for longer than 60 seconds. The device continues to operate but may not provide prescribed therapy.	Do not pause therapy or power Off the device while performing the following steps. Assess the device after each step. Continue to next step only if alarm remains unresolved. 1. Check the wound dressing for air leaks. Look for loose or decompressed dressing appearance, listen for air movement around the dressing and feel for areas less compressed or cooler in temperature. Address any identified leaks with transparent film or adhesive gel patches. 2. Ensure all connections are secure. - Dressing and canister tubing quick click connectors. - Y-connector quick click connectors, if applicable. 3. Disconnect the canister tubing from the dressing tubing by applying pressure to the canister tubing quick click connector and gently pulling the connectors apart. Close the tethered caps of both connectors. - If the alarm continues, a leak exists within the canister or at the canister to device connection. Replace the canister. Refer to “Removing/changing canister” section of manual for more details. Contact your Smith & Nephew authorised representative if the alarm continues after restarting therapy. - If the alarm resolves, a leak exists within the wound dressing or tubing. Reassess and replace as needed. **NOTE:** If Low Vacuum alarm is due to a leak in system, the Leak alarm may also be triggered while the Low Vacuum alarm is active.
High vacuum alarm • Status indicator illuminates yellow. • Audible alarm sounds every 20 seconds. • Audible alarm cannot be paused. 	The system has detected a high vacuum condition (>15mmHg above the therapy set point), potentially due to device malfunction. Device stops delivering therapy.	1. Power Off and restart the device. 2. If the alarm recurs there is a potential malfunction of the device. Contact your Smith & Nephew authorised representative.

Alarm status with display screen	Cause	Remedy
Over vacuum alarm • Status indicator illuminates yellow. • Audible alarm sounds every 20 seconds. • Audible alarm cannot be paused. 	The system has detected an excessively high vacuum (>235mmHg), potentially due to device malfunction Device stops delivering therapy.	1. Power Off and restart the device. 2. If the alarm recurs there is a potential malfunction of the device. Contact your Smith & Nephew authorised representative.
Blockage • Status indicator illuminates yellow. • Audible alarm sounds every 20 seconds. • Audible alarm may be paused for approximately 2 minutes by pressing the Pause Alarm icon on the screen. 	The system has detected a blockage within the canister, or the tubing or the internal canister filter is covered with exudate, which may occur even if canister does not appear visibly full. Device continues to operate but may not provide the prescribed therapy.	Do not pause therapy or power Off the device while performing the following troubleshooting steps. Assess the device after each step. Continue to the next step only if the alarm remains unresolved. 1. If one dressing is connected to the device, press the Home icon to navigate to the Home screen and ensure that the Y-Connect toggle icon is set to Y-Connect OFF. 2. Ensure all tubing and connections are free of any obstructions or kinks. 3. Disconnect the canister tubing from the dressing tubing by applying pressure to the canister quick click connector and gently pulling the connectors apart. Leave open the tethered cap of the canister quick click connector and close the tethered cap of the dressing connector. - If the alarm continues, the blockage exists within the canister. Replace the canister. Refer to “Removing/ changing canister” section of manual for more details. Contact your Smith & Nephew authorised representative if the alarm continues after restarting therapy. - If the alarm resolves, the blockage exists within tubing of the dressing. Reassess and replace as needed. **NOTE:** Device orientation, rate at which fluid enters the canister and how exudate solidifies can impact filter occlusion. To optimize canister volume and alarm functionality, keep the device in the upright position.

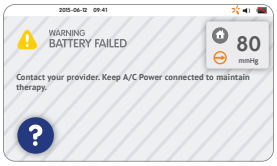
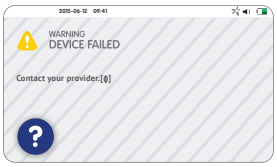
IMPORTANT: This guide is intended as a technical troubleshooting guide only. It does not constitute medical advice and appropriate medical attention must always be sought in the event that a clinical issue is suspected.

Alarm status with display screen	Cause	Remedy
Blockage continued		**Caution – Lack of alarms** • A Y-connector should be used when applying two dressings to a single wound. Setting Y-Connect On when only one dressing is connected to the device may cause nuisance alarms. Setting Y-Connect Off when two dressings are connected to the device may prevent blockage alarm from sounding. When Y-connecting two dressings to the device, regular monitoring of the wound is recommended. Ensure the dressing is fully compressed and firm to the touch. The system will only detect a blockage if both connections are blocked. The system will not detect a blockage existing in one of the Y-connected dressings; therapy will not be delivered through the blocked dressing. • The blockage alarm will occur when the system detects a blockage between the canister and where the dressing tubing interfaces with the transparent film. A blockage within the wound dressing will not be detected by the system. • If a blockage is present in the system but an air leak occurs between the blockage and the device, the alarm may not assert. Ensure that all connections are secure and there are no air leaks present in the system. Potential sources of air leaks include: - Cracked or damaged canister. - Misplaced or worn o-ring within the quick click connector. - Misplaced or worn o-ring on the device inlet port. - Damaged or tear in the dressing tubing or quick click connector.

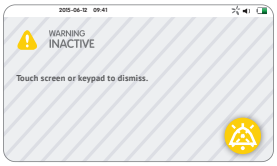
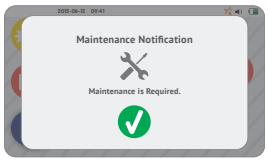
Alarm status with display screen	Cause	Remedy
Canister Full • Status indicator illuminates yellow. • Audible alarm sounds every 20 seconds. • Audible alarm may be paused for approximately 2 minutes by pressing the Pause Alarm icon on the screen. 	The system has detected the canister is nearly full or the internal canister filter is covered with exudate, which may occur even if canister does not appear visibly full. Device continues to operate but may not provide the prescribed therapy.	Pause therapy before performing the following troubleshooting steps. Assess the device after each step. Continue to the next step only if the alarm remains unresolved. 1. Replace canister and start therapy. Refer to “Removing/changing canister” section of manual for more details. 2. Inspect all tubing and connections for any obstructions or kinks. If alarm continues, contact your Smith & Nephew authorised representative for assistance. **NOTE:** Device orientation, rate at which fluid enters the canister and how exudate solidifies can impact filter occlusion. To optimize canister volume and alarm functionality, keep the device in the upright position.
Leak • Status indicator illuminates yellow. • Audible alarm sounds every 20 seconds. • Audible alarm may be paused for approximately 2 minutes by pressing the Pause Alarm icon on the screen. 	The system leak is greater than the allowable maximum leak threshold for >45 seconds. The device continues to operate but may not provide prescribed therapy.	Do not pause therapy or power Off the device while performing the following troubleshooting steps. Use the onscreen flow meter to help find and correct sources of the leak. Assess the device after each step. Continue to next step only if alarm remains unresolved. 1. Check the wound dressing for air leaks. Look for loose or decompressed dressing appearance, listen for air movement around the dressing and feel for areas less compressed or cooler in temperature. Address any identified leaks with transparent film or adhesive gel patches. 2. Ensure all connections are secure. - Dressing and canister tubing quick click connectors. - Y-Connector quick click connectors, if applicable. **Caution - lack of alarms** When a significant air leak is present in system, the Leak alarm will assert. However, if a blockage is present within system it may prohibit detection of a significant leak by the device, resulting in no alarm assertion. Potential sources of a blockage include: • Physical occlusion in wound dressing (clot in filler, compacted gauze, high volume viscous fluid). • Physical occlusion in tubing (kink in canister tubing, clot in tubing). • Misaligned dressing opening to RENASYS® Soft Port aperature. Check dressing regularly to ensure therapy is being delivered.

IMPORTANT: This guide is intended as a technical troubleshooting guide only. It does not constitute medical advice and appropriate medical attention must always be sought in the event that a clinical issue is suspected.

Alarm status with display screen	Cause	Remedy
Low Battery • Status indicator illuminates yellow. • Audible alarm sounds every 20 seconds. • Audible alarm may be paused for approximately 15 minutes by pressing the Pause Alarm icon on the screen. • The touchscreen dims to conserve battery life. 	Battery has up to 2 hours therapy time remaining. Upon battery depletion the device will stop delivering therapy and power Off.	1. Plug device into an electrical (AC) outlet as soon as possible. The device can be plugged into an electrical (AC) outlet to charge the battery without causing interruption to active therapy.
Critical Battery • Status indicator illuminates yellow. • Audible alarm sounds every 20 seconds. • Audible alarm may be paused for approximately 2 minutes by pressing the Pause Alarm icon on the screen. • The touchscreen dims to conserve battery life. 	The battery has only 3 minutes of therapy time remaining. Upon battery depletion the device will stop delivering therapy and power Off.	1. Plug device into an electrical (AC) outlet as soon as possible. The device can be plugged into an electrical (AC) outlet to charge the battery without causing interruption to active therapy.

Alarm status with display screen	Cause	Remedy
Battery Failed • Status indicator light illuminates yellow when the device is powered On. • There is no audible alarm.. **NOTE:** Battery Failure alarm only displays when device is connected to electrical (AC) power and powered On. 	Battery within device has failed to charge. Therapy can be continued only by keeping the device plugged into electrical (AC) power. Device stops delivering therapy and powers Off. It will not power On again unless plugged into an electrical (AC) outlet.	1. If the device has been exposed to temperatures outside its recommended temperature range, let the device return to room temperature. 2. Plug device into an electrical (AC) outlet; the device will not operate on battery power. Contact your Smith & Nephew authorised representative to obtain a replacement device.
Device Failed • Status indicator illuminates yellow. • Audible alarm sounds every 20 seconds. • Audible alarm cannot be paused 	The device has an unrecoverable error, potentially due to an internal hardware or software error. Device stops delivering therapy.	1. Power Off and restart device. 2. If alarm recurs note the failure code and contact your Smith & Nephew authorised representative.

IMPORTANT: This guide is intended as a technical troubleshooting guide only. It does not constitute medical advice and appropriate medical attention must always be sought in the event that a clinical issue is suspected.

Alarm status with display screen	Cause	Remedy
Inactive • Status indicator illuminates yellow. • Audible alarm sounds every 20 seconds. 	The device is powered On and has been left without user interaction for longer than 15 minutes. Device continues to operate.	1. Touch anywhere on the screen to resolve alarm. 2. Select vacuum setting and start therapy or power Off device until therapy is required.
Annual Maintenance • Status indicator illuminates yellow. • Audible alarm sounds every 20 seconds.. 	The device is nearing time for the annual maintenance check. Therapy can be continued. The annual maintenance notification will display every time the device is powered On. Device continues to operate.	1. Press the Accept icon to close this notification screen and continue to the Home screen. Continue therapy as planned. 2. At the conclusion of the patient's therapy, notify your authorised service provider that annual maintenance is required. The authorised service provider will verify the device is in proper working order and reset the alarm timer.

RENASYS◇ GO troubleshooting

Alarm status with display screen	Cause	Remedy
Low vacuum alarm		
! WARNING ! LOW VACUUM Vacuum level is lower than NPWT set point by >15mmHg. • Audible alarm will beep 2 times every 20 seconds. • Status/alarm indicator light will illuminate solid yellow. • Once corrected, alarm will automatically reset and status/alarm indicator will return to solid green. ! AUDIO PAUSED ! LOW VACUUM • Pressing audio pause button will pause audible alarm for approximately 2–3 minutes.	Device is unable to achieve selected vacuum level due to internal device malfunction or a significant leak in the system.	1. With device actively creating vacuum, check wound dressing for air leaks. Look for loose or decompressed dressing appearance, listen for air movement around dressing and feel for areas less compressed or cooler in temperature. Address identified leaks with transparent film or adhesive gel patch. 2. Ensure the following connections are secure: - Orange quick click connector between Soft Port and canister tubing. - Secure engagement of canister to device. - Y-connector orange quick click connectors, if present. **NOTE:** If low vacuum alarm is due to a leak in system, the high flow/leak alarm may also activate while low vacuum alarm is active. If over vacuum alarm indicator activates along with low vacuum alarm, follow troubleshooting steps for over vacuum alarm.
High vacuum alarm		
! THERAPY STOP ! HIGH VACUUM Vacuum level is higher than NPWT set point by >15mmHg. • Vacuum safety switch will operate and device will stop delivering therapy. • Audible alarm will beep 2 times every 20 seconds. • Status/alarm indicator will illuminate solid yellow. • This audio alarm cannot be paused and must be investigated by healthcare provider immediately and corrected.	Device has detected a high vacuum condition potentially due to line blockage or device malfunction.	1. Press and hold power button for 2 seconds to turn device OFF. 2. Inspect connections and tubing to ensure they are free of obstructions. Ensure there are no kinks in canister tubing. 3. Replace canister. 4. Turn device back ON by pressing and holding power button for 2 seconds. If alarm condition continues, device may have malfunctioned. Contact your Smith & Nephew authorised representative.

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Alarm status with display screen	Cause	Remedy
Over vacuum alarm		
! THERAPY STOP ! OVER VACUUM ! THERAPY STOP ! Restart Device The system has encountered an excessively high vacuum (of >235mmHg). • Vacuum safety switch will operate and device will stop delivering therapy. • Audible alarm will beep 2 times every 20 seconds. • Status/alarm indicator will illuminate solid yellow. • This audio alarm cannot be paused and must be investigated by healthcare provider immediately and corrected.	Device has reached high vacuum level (>235mmHg).	1. Press and hold power button for 2 seconds to turn device OFF. 2. Inspect connections and tubing to ensure they are free of obstructions. Ensure there are no kinks in canister tubing. 3. Replace canister. 4. Turn device back ON by pressing and holding power button for 2 seconds. If alarm condition continues, device may have malfunctioned. Contact your Smith & Nephew authorised representative.
Complete blockage/canister over-capacity		
! WARNING ! BLOCKAGE/FULL Device detects a complete blockage in vacuum circuit. There is no negative pressure at wound site. • Audible alarm will beep 2 times every 20 seconds. • Status/alarm indicator will illuminate solid yellow. • Once corrected, alarm will automatically reset and the status/alarm indicator will return to solid green. ! AUDIO PAUSED ! BLOCKAGE/FULL • Pressing audio pause button will pause audible alarm for approximately 2–3 minutes	There is a complete blockage in system; this includes a canister where contents have exceeded maximum volume capacity or in the instance that the internal canister filter is covered with exudate.	1. Check canister. If contents have reached maximum volume indication (300ml or 750ml fill line), replace canister. 2. Inspect connections, tubing and Soft Port aeration disc (located on Soft Port, near the orange quick click connector) to ensure they are free of obstructions. Ensure there are no kinks in canister tubing. 3. Disconnect Soft Port from canister tubing at orange quick click connector. Insert tethered cap into Soft Port connector. Allow air to flow freely into canister tubing. - If alarm condition continues, there is a potential issue with the device or canister. Replace canister and contact your Smith & Nephew authorised representative. - If alarm condition resolves, a blockage is present within the Soft Port. Reassess and replace as needed. **Caution:** Do not wait for alarm activation to change canister. At point of alarm activation, canister contents have exceeded maximum volume capacity, potentially impacting device alarm functionality. **NOTE:** Device and canister should be kept in an upright orientation to optimise canister over-capacity alarm functionality while maximising canister volume.

Alarm status with display screen	Cause	Remedy
Complete blockage/canister over-capacity continued		**Caution - lack of alarms** • If partial blockage occurs, the change in pressure status detected by device may not be significant enough to trigger alarm activation. Over time if blockage reaches point of full occlusion, complete blockage alarm will activate. • Blockage formation within wound dressing will not be detected by system as it has occurred outside of monitored vacuum circuit, but can affect pressure status at the wound. Appropriately frequent monitoring of wound dressing is recommended to confirm adequate delivery of therapy. • In the event of heavy or viscous drainage, drainage with sediment or when blood is present, regular monitoring and more frequent dressing changes may be required. • If a complete blockage is present in the system, but an air leak occurs between blockage and device, the alarm may not activate. Ensure all connections are secure and no air leaks are present in system. Potential sources of air leaks include: - Misplaced or worn O-ring on the device inlet port, located between the device and canister. - Tear in Soft Port. - Misplaced or worn O-ring within the quick click connector (between the Soft Port and canister tubing). - Cracked or damaged canister. • When using a Y-connector to connect two Soft Ports to the same device, a complete blockage alarm will not activate unless a complete blockage is present in both Soft Ports. If a partial blockage is present in one or both Soft Ports, the complete blockage alarm will not activate. When Y-connecting within a NPWT system, regular monitoring of both wound dressings is recommended. Ensure that all dressings are fully compressed and firm to the touch. **NOTE:** For RENASYS◇ F/P or G/P wound dressing kits, the complete blockage alarm will only activate if a complete blockage occurs within the canister tubing. There is no blockage detection in the dressing tubing.

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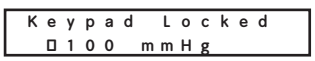
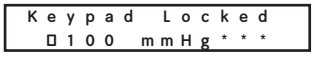
Alarm status with display screen	Cause	Remedy
High flow/leak alarm		
! WARNING ! LEAK Device detects a significant leak in the system. • Alarm will beep 2 times every 20 seconds. • Status/alarm indicator will illuminate solid yellow. • Once corrected, alarm will automatically reset and status/alarm indicator will return to solid green. ! AUDIO PAUSED ! LEAK • Pressing audio pause button will pause audible alarm for approximately 2-3 minutes.	There is a significant leak in the system. This could include an air leak around the dressing or a poor seal at one of the connectors between the dressing, Soft Port, canister or device.	1. With device actively creating vacuum, check wound dressing for air leaks. Look for loose or decompressed dressing appearance, listen for air movement around dressing and feel for areas less compressed or cooler in temperature. Address identified leaks with transparent film or adhesive gel patch. 2. Ensure the following connections are secure: - Orange quick click connector between Soft Port and canister tubing. - Secure engagement of canister to device. - Y-connector orange quick click connectors, if present. 3. Disconnect Soft Port from canister tubing at orange quick click connector and insert tethered cap into both connectors. - If alarm condition continues, there is a potential issue with the device or canister. Replace canister and contact your Smith & Nephew authorised representative. - If alarm condition resolves, an air leak is present within the wound dressing or Soft Port. Reassess and replace as needed. **NOTE:** An air leak may result in a pressure drop occurring within the system. As a result, the low vacuum alarm may also activate while the high flow/leak alarm is active. **Caution – Lack of alarms:** Under specific circumstances, a significant air leak may occur in system without device activating a high flow/leak alarm. This may be due to partial blockage between source of air leak and device, prohibiting detection of the leak by device. As a result, alarm will not activate. Over time, if blockage reaches point of full occlusion, the complete blockage alarm will activate. Read complete blockage/canister over-capacity alarm troubleshooting for instruction on locating the system blockage. Check wound dressing regularly to ensure it is fully compressed and firm to the touch.

Alarm status with display screen	Cause	Remedy
Inactive alarm		
 Device has been left in standby mode for longer than 15 minutes. • Alarm will beep 2 times every 20 seconds. • Status/alarm indicator will illuminate solid yellow. • Once corrected, alarm will automatically reset and status/alarm indicator will return to solid green.  • Pressing audio pause button will pause audible alarm for approximately 2-3 minutes. • Alarm can only be paused once.	Device has been left in standby mode without any keys being pressed for longer than 15 minutes.	Either select pressure setting and start therapy or turn device OFF until therapy is required.
Battery		
See battery status and alarm section of manual for screen messages.	Battery partially discharged or depleted.	Plug unit into AC mains power to charge battery.
Keypad lock on		
 When lock is active, Keypad lock will illuminate solid blue.	User interface is locked.	Unlock by pressing and holding keypad lock button for 2 seconds.
Homecare use lock on		
 When lock is active, Keypad lock will illuminate solid blue. (Feature is available only on the RENASYS◇ GO: REF 66801496)	User interface is locked.	Unlock by simultaneously pressing and holding the keypad lock and audio pause buttons for 5 seconds.

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Alarm status with display screen	Cause	Remedy
Device failed alarm		
 Device has an unrecoverable error. • Status/alarm indicator will illuminate solid yellow.	Internal hardware or software error.	Contact your Smith & Nephew authorised representative.
Device not calibrated alarm		
 Device will not operate. • Alarm will beep 2 times every 20 seconds. • Status/alarm indicator will illuminate solid yellow.	Service and repair required	Contact your Smith & Nephew authorised representative.
Battery failed alarm		
 Battery within device has failed. • Battery status bottom indicator will illuminate solid yellow. • Therapy can only be continued by keeping device plugged into AC mains power. • Status/alarm indicator will illuminate solid yellow. **NOTE:** This will only display when connected to AC mains power.	Internal hardware failure.	Contact your Smith & Nephew authorised representative.

Notes

RENASYS◇ FAQ

Q What is the suction pressure of your machine or the range of pressure that the device achieves?

A RENASYS TOUCH, -25mmHg to -200mmHg

RENASYS GO, -40mmHg to -200mmHg

Q Is the pressure pre-set?

A The pressure on RENASYS TOUCH is pre-set to -80mmHg. It may then be adjusted to the desired level on the RENASYS GO device. However the device resumes at the same level of pressure as was set when it was last turned off or put on standby.

Q Can it be changed?

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

Q Is there an Variable Intermittent Mode and when should I use it?

A The RENASYS TOUCH is able to deliver variable intermittent and adjustable intermittent NPWT using tailored time settings defined by the clinician.

The RENASYS GO is able to provide intermittent therapy at a 5 minute on 2 minute off interval.

Experimental studies have shown improvements in the rate of granulation tissue formation, wound contraction and blood flow with intermittent and variable NPWT compared with continuous NPWT.[27-30] Some reports suggest that intermittent NPWT may be painful in susceptible patients.[31] Patients being treated with variable NPWT have been shown to report less pain compared with intermittent pressure.[28]

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

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

A Canisters should be changed at least once a week, whenever there is a change of patient or in the event the canister contents reach maximum volume indication. Do not wait for canister over-capacity alarm activation to change canister.

A thorough assessment of the device and wound should be performed regularly.

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

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

Q How long does the battery last?

A RENASYS TOUCH: up to 16 hours

RENASYS GO: up to 20 hours

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

A RENASYS◇ TOUCH is 0.967kg. This may come with a shoulder strap and carry bag, which may also be ordered separately. The device can also be mounted on an IV pole and bed rail with attachments.

RENASYS GO is 1 kg. This may come with a shoulder strap and carry bag, which may also be ordered separately. Please contact your Smith & Nephew provider or refer to appendix product guide.

Q What is the interface with the wound?

A For the RENASYS systems, the wound fillers are foam or gauze.

Q How do you handle exposed tendon or bone?

A Exposed tendons and bone should be covered with natural tissue or a non-adherent dressing layer prior to applying the Negative Pressure Wound Therapy (NPWT) dressing.

Q How do I know if the RENASYS◇ TOUCH and GO therapy device is working?

A While the RENASYS TOUCH and 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. For RENASYS GO, If the device is set to CONTINUOUS mode the selected pressure is displayed on the screen. If the device is set to INTERMITTENT mode, the gauge will show 0 pressure during "off time" and the set pressure while vacuum is occurring.

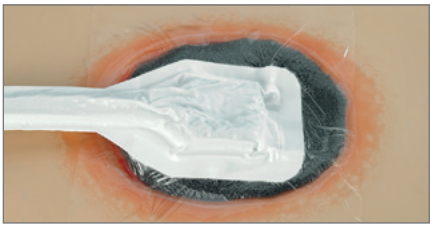
Frequent visual monitoring of the therapy by the clinician or patient if at home is recommended to ensure the therapy is active.

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

A

Gauze with drain

Gauze with Soft Port



Foam with Soft Port

RENASYS◇ ORDERING INFORMATION

RENASYS TOUCH NPWT System

RENASYS TOUCH Device

RENASYS TOUCH

- Pump and power supply
- Power cord
- RENASYS TOUCH Clinician User Manual
- RENASYS TOUCH Home Healthcare User Manual

Product code 66802134

RENASYS TOUCH canisters

RENASYS TOUCH 300ml canister with solidifier

- Sealed canister
- Solidifier
- Canister tubing

Product code 66801273

RENASYS TOUCH 300ml canister without solidifier

- Sealed canister
- Canister tubing

Product code 66801275

RENASYS TOUCH 800ml canister with solidifier

- Sealed canister
- Solidifier
- Canister tubing

Product code 66801274

RENASYS TOUCH

Accessories

RENASYS TOUCH Carry Bag

Product code 66801277

RENASYS TOUCH Carry Straps

Product code 66801276

RENASYS TOUCH IV / Bed pole clamp

Product code 66801278

RENASYS TOUCH Transit case

Product code 66801279

RENASYS TOUCH Odor Filter

Product code 66801284

RENASYS TOUCH O-Ring

Product code 66801283

RENASYS◇ GO NPWT System

RENASYS GO device

RENASYS GO

- Pump and power supply
- Power cord
- RENASYS GO Clinician User Manual
- RENASYS GO Home Healthcare User Manual

Product code 66801496

RENASYS GO Accessories

RENASYS GO Carrying case

Product code 66800162

RENASYS GO Carry Strap

Product code 66800163

RENASYS GO O Rings

Product code 66800603

RENASYS GO Odour Filters

Product code 66800061

RENASYS GO canister

RENASYS GO Large Canister (750ml)

5 per case

- Sealed canister
- Solidifier
- Canister tubing

750ml with solidifier
Product code 66800916

RENASYS GO Canister (300ml)

5 per case

- Sealed canister
- Solidifier
- Canister tubing

300ml with solidifier
Product code 66800914

RENASYS◇ Dressing Kits

Foam Dressing Kit with Soft Port

RENASYS-F

Small
- Foam block 10cm x 8cm x 3cm
- RENASYS Transparent Film
- RENASYS Soft port

Product code 66800794

Medium
- Foam block 20cm x 12.5cm x 3cm
- 2 RENASYS Transparent Films
- RENASYS Soft port

Product code 66800795

Large
- Foam block 25cm x 15cm x 3cm
- 3 RENASYS Transparent Films
- RENASYS Soft port

Product code 66800796

X-Large
- Foam block 48cm x 41cm x 1.5cm
- 6 RENASYS Transparent Films
- RENASYS Soft port

Product code 66800797

RENASYS -AB Abdominal Dressing Kit with Soft Port

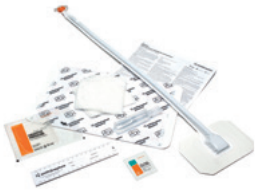
- 2 Foam blocks 40.5cm x 27.5cm x 2.5cm
- Organ protection layer 80cm x 66cm
- 6 RENASYS Transparent Films
- RENASYS Soft port

Product code 66800980

Gauze Dressing Kit with Soft Port

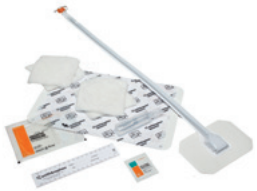
RENASYS-G

Small
- AMD gauze dressing 15cm x 17cm
- RENASYS Transparent Film
- Non-adherent gauze
- RENASYS Soft Port
- SECURA No-Sting Barrier Film Wipe
- Saline
- Paper Ruler



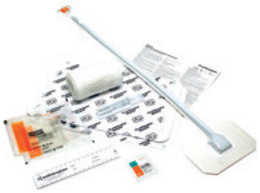
Product code 66800933

Medium
- 2 AMD gauze dressing 15cm x 17cm
- RENASYS Transparent Film
- Non-adherent gauze
- RENASYS Soft Port
- SECURA No-Sting Barrier Film Wipe
- Saline
- Paper Ruler



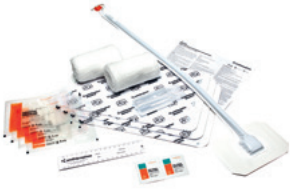
Product code 66800934

Large
- AMD gauze roll 11.4cm x 3.7m
- 2 RENASYS Transparent Films
- 2 Non-adherent gauze
- RENASYS Soft Port
- SECURA No-Sting Barrier Film Wipe
- Saline
- Paper Ruler



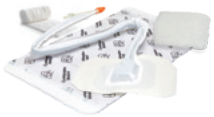
Product code 66800935

X-Large
- 2 AMD gauze rolls 11.4cm x 3.7m
- 3 RENASYS Transparent Films
- 4 Non-adherent gauze
- RENASYS Soft Port
- 2 SECURA No-Sting Barrier Film Wipes
- 2 salines
- Paper ruler



Product code 66800936

Sterile Gauze Dressing Kit with Soft Port
- AMD gauze roll 11.4cm x 3.7m
- AMD gauze dressing 15cm x 17cm
- 3 RENASYS Transparent Films
- RENASYS Soft Port



Product code 66800961

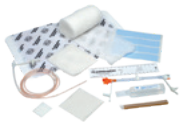
RENASYS◇ Drain kits

Gauze Drain Dressing Kits

RENASYS-G Gauze dressing kit with drain

- 1 Drain (available in 4 configurations listed)
- 1 RENASYS Quick-Click Adapter
- 1 Non-Adherent Gauze 7.5cm x 20cm
- 1 AMD gauze roll 11.4cm x 3.7m
- 1 AMD gauze sponge 10cm x 10cm
- 1 RENASYS Transparent Film
- 4 Strips waterproof tape
- Ostomy paste
- 1 SECURA No-Sting Skin Prep barrier film wipes
- Saline
- Paper ruler

10Fr Round Drain Gauze Dressing Kit
Product code 66801255



10mm Flat Drain Gauze Dressing Kit
Product code 66801256

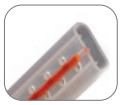
15Fr Channel Drain Gauze Dressing Kit
Product code 66801257

RENASYS Drain Kits

Drain Accessory Kits

- 1 Drain (available in 4 configurations listed)
- 1 RENASYS Quick-Click Adapter
- 2 Strips waterproof tape

10Fr Round Drain
Product code 66801251



10mm Flat Drain
Product code 66801252

15Fr Channel Drain
Product code 66801253

RENASYS Accessories

Kit Accessories

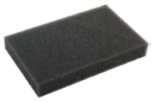
Smith & Nephew Gauze Wound Dressing

- 5 rolls of AMD gauze rolls 11.4cm x 3.7m
- 1 SECURA No-Sting Barrier Film Wipe

Product code 66802127

Smith & Nephew Foam Wound Dressing

- 1 Foam block 10cm x 13cm x 1.5cm per pouch



Product code 66801021

RENASYS Transparent film

- 10 Transparent Films 20cm x 30cm per pouch

Product code 66800394

RENASYS Transparent film X-Large

- 5 Transparent Films 38cm x 60cm per pouch

Product code 66800853

RENASYS Y-Connector

- 1 Y-Connector per kit

Product code 66800971

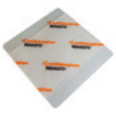
RENASYS Soft Port Stand-Alone

- 1 Soft Port per kit

Product code 66800799

RENASYS Adhesive Gel Patch

- 10 gel patches with double sided silicone adhesive hydrogel10cm x 7cm per carton



Product code 66801082

Notes

REFERENCES

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Notes

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