Smith+Nephew

RENASYS® EDGE

Negative Pressure Wound Therapy

Clinician User Manual

RENASYS® EDGE device 66803126 only

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Welcome to your RENASYS® EDGE pump user manual

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Contents

Introduction

This user manual contains important information regarding the safe and effective operation of the RENASYS° EDGE Negative Pressure Wound Therapy (NPWT) pump. This pump is only to be prescribed by a clinician and is intended for use by, or on the direction of, a trained and licensed physician. This manual is intended to aid in the training of personnel and to provide a reference for experienced users. Also included are instructions for operating the pump, preventative maintenance, cleaning and return of the pump. This user manual is intended only as a guide. For medical questions, please consult a physician.

Intended Environmental Settings

The RENASYS° EDGE pump is intended for use in acute care settings and other professional healthcare environments where product use is conducted by or under the supervision of a qualified clinician. The pump is also intended for use in home healthcare settings where product use is conducted by or under the supervision of a qualified clinician.

To ensure that the pump is safe for use in residential settings, this pump is compliant with the IEC medical equipment and medical electrical safety standard IEC 60601-1-11 for use of medical devices in the home healthcare environment. This standard includes the use of a double insulated Class II power supply.

Information For Your Patients

Prior to discharging your patient with the RENASYS° EDGE pump and User Manual, listed below are some topics they should know. These topics are covered in both the clinician and home healthcare user manuals.

- Introduction (Warnings + Precautions)
- Pump Description and Navigation
- Pump Setup
- Alarm, Alerts and Troubleshooting
- Accessories

Patient training on these topics will enable the patient to use the RENASYS° EDGE pump safely and effectively at home. Following training, patients should be able to successfully troubleshoot issues that arise, this will allow them to get the most benefit out of their treatment while at home.

Important Information Monitoring NPWT

- Carefully monitor the patient, pump, and dressing to determine if there are any signs of bleeding, exudate accumulation (pooling), infection, maceration, or loss of 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.

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 pump, canister and tubing 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 the device's ability to remove fluid or increase the chance of occlusion formation.
- A full canister and/or incorrect pump orientation can contribute to loss of NPWT and exudate accumulation within the wound, which could lead to maceration, infection, or bleeding.

Introduction (cont.)

- 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 Negative Pressure Wound Therapy (NPWT) is delivered.
- Review Contraindications, Warnings & Precautions before use.

Indications For Use

The RENASYS° EDGE pump is indicated for patients who would benefit from a suction pump (NPWT), as it may promote wound healing via removal of fluids, including irrigation fluids and body fluids, wound exudate and infectious materials.

Appropriate wound types include:

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

Important information when using the RENASYS° AB Abdominal Kit with Soft Port

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

Contraindications

Use of the RENASYS° EDGE pump is contraindicated in the presence of:

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

Clinician Prescription

Prior to placement of the RENASYS° EDGE pump, the clinician treating the wound must assess how to best use the pump, canister and tubing for a wound. It is important to carefully assess the wound and patient to ensure clinical indications for NPWT are met.

All prescriptions should include:

- Wound location, size and type
- Smith+Nephew Wound Dressing Kit
- Pressure settings
- Frequency of dressing changes
- Adjunctive dressings

Warnings and Precautions

Before Use

General

- As a condition of use, the pump should only be used by qualified and authorized personnel. Users must have necessary knowledge of the specific medical application for which Negative Pressure Wound Therapy (NPWT) is being used.
- The product must be used in accordance with this user manual and all applicable labeling.
- Patient size and weight should be considered when prescribing therapy, particularly in pediatric use.
- Patients suffering from abnormal hemostasis or treated with anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using hemostatic products that, if disrupted, may increase the risk of bleeding.
- Use RENASYS° EDGE 300ml canisters with patients at high risk of bleeding.
- Due to its smaller diameter, the RENASYS°-G 10Fr Round Drain Gauze Kit and Accessory Kit are not recommended for use with the RENASYS° EDGE pump, as reduced pressure in the wound bed may lead to pooling or maceration.
- Use of NPWT presents a risk of tissue ingrowth. Tissue in-growth may be reduced by:
  - reducing the level of pressure applied to the wound,
  - using a wound contact layer, or
  - increasing the frequency of dressing changes.

Appropriate wound sites

- The RENASYS° EDGE system should only be used on wounds identified in the indications for use section. NPWT should not be applied to any wound types listed in the contraindications section.
- NPWT should not be placed directly over the patient's nerves, including the vagus nerve, as this could impact their functionality.
  - Do not use directly on **exposed** blood vessels, organs or underlying structures.
  - **Remove sharp edges** such as bone fragments or **cover** with non-adherent gauze prior to initiating therapy, due to risk of puncturing organs or blood vessels drawn closer under the action of negative pressure.
  - **Cover** underlying structures, such as **bone, tendons, ligaments and nerves,** with natural tissue or a non-adherent dressing layer prior to applying the dressing to minimize the risk of damage from direct contact with the dressing.
  - The RENASYS° EDGE pump should not be used for airway aspiration, or surgical suction or endoscopic closure of esophageal anastomotic leak.
- The RENASYS° EDGE pump should not be used in the open abdomen, unless it is being used with the RENASYS° AB Abdominal Kit with Soft Port and within a hospital setting.

Two wound sites

- The RENASYS° Y-Connector should not be used in the two wound configuration if one of the wounds is located in the open abdomen.
- When using a RENASYS° Y-Connector, the patient should be monitored on a more frequent basis. The system will only detect a blockage if both connections are blocked. Regularly monitor the patient to ensure both dressings remain compressed.

During Use

Monitoring

- Monitor patients and canister contents for signs of bleeding. If active bleeding is observed, immediately **discontinue NPWT**, take appropriate measures to control bleeding and contact treating clinician.
- **More frequently monitor** the patient, pump and wound dressing, if patients are or may be:
  - Suffering from wounds in close proximity to blood vessels or delicate fascia,
  - 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, suffering from difficult wound hemostasis or have friable blood vessels or organs,
  - Suffering from untreated malnutrition, or
  - Non-compliant or combative.

Warnings and Precautions (cont.)

- Monitor patient for any signs of local of systemic infection. As Negative Pressure Wound Therapy is not intended to directly treat infection, **contact treating clinician immediately** if there are any signs of systemic infection or advancing infection at wound area.

Dressings

- Wound dressings should only be changed by clinicians and in accordance with the dressing change frequency stated in the dressing user manual. See dressing kit user manuals for instruction on dressing application and removal.
- The pump is only to be used with Smith+Nephew authorized components, dressing kits and accessories.

Accessories/AC power

- AC mains power can only be removed by disconnecting the AC power supply. Ensure pump can always safely be removed from mains power in an emergency situation.
- The electrical installation of the room must comply with the appropriate electrical wiring standards.
- Only use the power supply provided by Smith+Nephew to charge the pump. Use of any other products has not been proven safe and effective with the RENASYS° EDGE pump.

Hygiene and sterility

- Users should wash their hands before and after disconnecting the pump from the dressing to reduce the risk of cross contamination.
- Before disconnecting the pump from the dressing, to reduce the risk of cross contamination, ensure that the quick click connectors are held:
  - higher than the pump and wound, and
  - away from where wound fluid may contaminate the patient or other people.
- RENASYS° EDGE pump, power supply and canisters are not provided sterile and should not be placed within a sterile field.

Pump operation

- Do not use the pump or any accessories if they are damaged or do not function correctly. Contact your Smith+Nephew representative if the RENASYS° EDGE pump emits an unusual noise, the display does not function correctly, or if the power indicator does not illuminate when the pump is plugged into charge.
- Do not use the RENASYS° EDGE power cord if any wires are frayed or exposed. Contact your Smith+Nephew representative for a replacement.
- Do not attempt to dismantle or modify the pump or any accessories. No maintenance can be performed by patients or caregivers.
- Do not operate the pump self-test feature in a dusty environment as it may damage the pump.
- Do not swallow any small parts removed from the device

Showering

- The pump and power supply contain electronic components and cannot be exposed to water. If water or other liquids get into the pump, turn it Off and consider changing the pump. If failure still occurs contact Smith+Nephew Medical, Ltd.
- When bathing or showering the patient, you must disconnect the pump and protect both ends of tubing using the tethered caps.

Pump placement

- Position pump, tubing and cables appropriately so that they do not wrap around the patient's neck or limb or cause a trip hazard. Be aware of tubing placement around children and animals.
- Ensure the patient cannot lie or sit on the pump and tubing as this may cause a pressure injury.
- When pump is set at 25 mmHg consider placing pump and tubing at the same height as or below the wound. This will ensure the prescribed level of therapy is delivered.

Continued overleaf ››