The use of the device is contraindicated in the presence of:

- Uncontrolled coagulopathy
- Exposed arteries, veins, or organs
- Necrotic tissue with eschar present
- Malignancy in wound bed exceeding 5cm/1.97in beyond wound margin
- Anastomotic sites

WARNINGs

1. Carefully monitors patients for signs of bleeding, which may lead to intratumor or hereditary hemorraghic episodes should ischemic injury. If such symptoms are observed, immediately discontinues therapy, removes dressing, controls bleeding, and treatment controls.

2. Patients suffering from comorbidities who are receiving anticoagulant therapy may have an increased risk of bleeding. During their therapy, patients with these conditions should consult a dermatologist about systemic anticoagulant products. If dizziness, may increase risk of bleeding.

3. Do not directly over exposed blood vessels or organs. Sharp edges such as bone fragments must be covered or removed prior to initiating therapy. Due to the risk of puncturing organs or blood vessels drawn closer under negative pressure, always place a sterile drape over the wound to contribute to NPWT loss and avoid accidental puncture of the organ or blood vessel.

4. NPWT has not been studied on pediatric patients. Patient size and weight should be considered when determining the negative pressure to be applied.

5. Foam or gauze must not be tightly packed or forced into any wound area. Proper pressure packaging with distribution of NPWT evenly across the wound. This may decrease the ability of the wound to properly contract and permit external seal to remain on wound.

6. In the event a debridement is required, disconnect device from the canister before starting the procedure to remove dressing only if the wound will interfere with the debridement.

7. The device is not MRI compatible. Do not bring device into the MRI environment. It is always advisable to remove dressing prior to imaging. Throughout wound healing should occur with each dressing change.

8. Do not use any devitalized or necrotic tissue. Gauze the wound bed and pad before NPWT.

9. If dressing failure, protect the wound area from exposure to moisture. Wound contact layer is a water-resistant dressing that can be used in combination with a skin sealant through the use of a skin sealant. When using a wet dressing, it is dry before dry dressing in the presence of debridement.

10. Universal precautions should be observed whenever working with potentially infectious materials.

11. Device and canister are non-sterile and should not be placed within a sterile field.

PRECAUTIONS RELATED TO FOAM

- Chronic
- Traumatic
- Abrasions or allografted wounds
- Ulcers (such as pressure or diabetic)
- Partial thickness burns
- Flaps and grafts

INDICATIONS FOR USE

RINASYS foam and RINASYS-GG gauze dressing kits with SoftPort are intended to be used in conjunction with the RENASYS® Negative Pressure Wound Therapy (NPWT) System. The RENASYS® Negative Pressure Wound Therapy (NPWT) System is recommended in these wounds.

1. If multiple pieces of foam or gauze are needed to fill the wound, the SoftPort should not be removed until all pieces are in place. If dressings are present, ensure all dressings are removed at the dressing change to minimize the risk of infection and possible infection.

2. NPWT should not remain for an duration of treatment. The length of therapy is dependent on the condition of the wound and the condition of the patient. It is important to consider the condition of the wound, including volume, drainage, the wound bed characteristics including tissue viability, and integrity of the wound.

3. Monitor regular monitoring of device and wound dressing during therapy to ensure therapeutic treatment and patient comfort.

4. See the instructions with Smith & Nephew authorized components. Use of any other products have not been tested or evaluated for use with RENASYS® therapy.

5. Ensure canister tubing and RENASYS SoftPort are installed completely and without any leaks to avoid air emboli in the canister circuit. Position device tubing and canal appropriately to avoid risk of trauma. Device tubing and canal should be protected from the flow of NPWT. Do not place the canister holder above the wound for RENASYS® devices and no higher for RENASYS® GO devices. To ensure that the canister holder is not placed too high, the patient and the patient’s caregiver should refer to your Smith & Nephew authorized provider for service.

6. CT scans and x-ray have the potential to interfere with functional performance of the device. Keep the device outside of a CT scan or x-ray scanner range.

7. In the event of heavy or viscous drainage, drainage with or without patient, should discontinue off the wound for RENASYS® devices and recommended therapy can be increased as required. Use of any other alcohol or irrigation devices have not been tested or evaluated for use with RENASYS® therapy.

8. Ensure RENASYS® devices are placed on a stable level surface. When placed on an uneven surface, device can become unbalanced as excess film contact.

DRESSING WOUNDS WITH FOAM OR GAUZE

Review Precautions Specific to Foam and Gauze before continuing. It is critical that foam is not forced into any wounds, particularly by bending or squeezing the foam. When bending or squeezing the foam, it is critical that foam is not forced into any wounds, particularly by bending or squeezing the foam. When bending or squeezing the foam, the foam should be kept flat and not forced into any wounds. When bending or squeezing the foam, the foam should be kept flat and not forced into any wounds.

Preparations Related to Foam

1. Foam should be cut to fit loosely into wound base. Do not force or tightly pack foam into any wound areas. The foam should not be used in wounds with pressure contact.

2. Do not place foam into a vacuum or uncompressed wounds, if a vacuum or uncompressed wounds, if a vacuum is used in wounds with pressure contact.

3. Do not cut foam in any wound base to avoid any foam fragments from falling into the wound. Rub edges of foam to prevent foam from landing in the wound. Remove loose fragments after cutting.

SPECIAL PRECAUTIONS TO GAUZE

1. Use of gauze as a filler in wounds that are in a weight bearing location or have moderate to heavy drainage is contraindicated. Should not be used for any wound that is over 5cm/1.97in beyond the wound margin. It is recommended in these wounds.

CLEAN AND DEBREDE

Use clear or opaque techniques for location, according to the patient’s state of consciousness. Throughout wound healing should occur with each dressing change.

1. Layer additional foam or gauze in the wound base to prevent any risk of infection. Ensure contact with the wound in the care of the patient. During the course of therapy, patient’s fluid levels must be closely monitored.

2. Avoid use of circumferential dressings except in cases of extreme vascular compromise or severe injury. Circumferential dressings may be used when the bridge, foam is recommended. In the case that gauze is used, it is critical to avoid the risk of heavy drainage, more frequent inspection of the dressing and dressing changes may be required. It is crucial to avoid the risk of heavy drainage, more frequent inspection of the dressing and dressing changes may be required.

3. Monitor for any signs of systemic infection or any signs of systemic infection or any signs of systemic infection. Infected wounds may require more frequent dressing changes. NPWT is not intended for the treatment of a systemic infection. NPWT should not be painful. If patient reports discomfort, consider reducing dressing pressure setting and use of a wound debridement to improve pain. NPWT should not be painful. If patient reports discomfort, consider reducing dressing pressure setting and use of a wound debridement to improve pain. NPWT should not be painful. If patient reports discomfort, consider reducing dressing pressure setting and use of a wound debridement to improve pain. NPWT should not be painful. If patient reports discomfort, consider reducing dressing pressure setting and use of a wound debridement to improve pain.