

24. If power supply or power cord is damaged, wires are frayed or exposed, do not use power.
Contact your Smith & Nephew representative for a replacement.
25. 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 800ml fill line).
Do not wait for the Canister Full alarm to sound to change canister.
26. Canisters are single use. 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 dressing tubing and canister tubing should be protected using tethered caps to avoid leakage of fluid and cross contamination.
30. Due to its smaller diameter, the RENASYS™-G 10Fr Round Drain Gauze Kit and Accessory Kit are not recommended for use with RENASYS TOUCH, as reduced pressure in the wound bed may lead to pooling or maceration.

Physician orders

Prior to placement of RENASYS TOUCH, the medical professional treating the wound must assess how to best use the system for an individual wound. It is important to carefully assess wound and patient to ensure clinical indications for Negative Pressure Wound Therapy (NPWT) are met.

All orders should include:

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

→ *ventilative tarp*

FAQs

Niduje talpa yra absorbuojanti gelis.

RENASYS System FAQ's

What is the flow rate of RENASYS TOUCH pumps?

9.25 Litres/minute free flow without canister and tub set.

What intrinsic mechanism is there in the RENASYS system to prevent backflow if machine is powered off?

Firstly the aeration disc (if Soft Port) or the CLP T-piece provides a flow of air that ensures that the air flow, once the machine is powered off, is away from the wound and towards the canister until the vacuum is dissipated. Secondly the gelling agent helps to retain the liquid in the canister (when the canister includes a solidifier).

How does RENASYS TOUCH monitor pressure?

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RENASYS TOUCH continuously monitors the pressure delivered and the air flow travelling through the system. If the expected airflow decreases below a pre-defined level, this correlates to a potential blockage and the device will inform the user with an alarm. RENASYS TOUCH also is able to auto correct the system when changes in pressure occur, to overcome a leak state. If a leak can't be compensated by the system, the device will inform the user with an alarm.

Can RENASYS TOUCH deliver and maintain pressure whilst above the wound?

Yes RENASYS TOUCH can deliver and maintain pressure when up to 90cm above the wound.

Can RENASYS TOUCH be taken on an aircraft?

Yes. Certified to all relevant standards that cover this environment.

What performance and safety checks are required between each patient?

- Pump cleaning following the directions provided in the service manual for RENASYS TOUCH.
- Device physical appearance check
- Functionality and alarm checks – complete functionality check, clinician mode, operation check, operation on battery check, blockage alarm check and restore presets as per directions provided in the RENASYS TOUCH service manual

What performance and safety checks are required on an annual basis?

Device vacuum checks as detailed in the RENASYS TOUCH Service manual.
Replace RENASYS TOUCH O-Ring and Odour filter as detailed in the RENASYS TOUCH Service Manual.

- The primary role of the first filter (the one facing towards the liquid in the canister) is to prevent liquid leaving the canister in a direction towards the pump. The secondary purpose of the first filter is to prevent bacteria from the canister leaving the canister in a direction towards the pump.
- The second filter provides odour protection.
- The third filter is at the exit of the canister to the pump. The primary role of the third filter is to prevent any bacteria that have not been stopped by the first filter progressing any further. The secondary purpose of the second filter is to prevent any liquid that might have breached the first filter, (e.g. due to mechanical failure), from progressing any further.

The mechanism by which these filters function is a combination of size exclusion and surface energy.

What materials are the RENASYS TOUCH canisters constructed from?

Body and Lid: Styrolution clearblend

Filters: The bacterial is hydrophobic and ePTFE membrane Solidifier

Clips: Valox 310

Tubing: Polyvinyl chloride (PVC)

Connector plug; nylon; zytel 101 F

Caps for Connector: Santoprene 271- 87

Are RENASYS TOUCH canisters sterile?

No these are not sterile

What is the maximum capacity of the RENASYS 300ml and 800ml canisters with and without solidifier?

The RENASYS canisters has a indication to measure its capacity. Within the design of the canister, there is also an additional space above this which is used to accommodate the impact of the gelling agent before the activation of the canister full alarm. Hence the solidifier does not affect the amount of fluid displaced in the canister. We do not specify the total capacity of the canister as this is dependent on the orientation of the canister/device when in use. The canister is designed to hold either 300ml or 800ml with or without gelling agent before the canister full alarm activation.

Battery life and Charging

What are the battery's operating conditions when charging?

Operational temperature 5°C to 40°C

Relative humidity 15% to 93% RH

Atmospheric pressure 700mbar to 1060 mbar

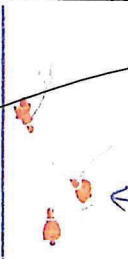




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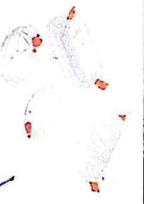
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RENASYS Accessories

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| SKU | Description | Image |
|----------|--|---|
| 66800971 | Y-Connector |  |
| 66800799 | RENASYS Soft Port |  |
| 66801021 | Foam Filler 10 x 12.5cm Pack 1 |  |
| 66800394 | NPWT LARGE DRAPE (FILM DRSG) 20cm X 30cm |  |
| 66800853 | RENASYS TRANSPARENT FILM XL 38cm x 60cm |  |

| SKU | Description | Image |
|----------------------------------|---|--|
| 66801082 | Gel Patch 10cm x 7cm |  |
| 66802127 | Medicated Gauze Procedure pack |  |
| 66801273 66801274 66801275 | 300ml Canister with Solidifier 800ml Canister with Solidifier 300ml Canister without solidifier |  |

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Menu

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Anticancer
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Smith & Nephew

Supplies for the day

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RENASYS[®] Soft Port

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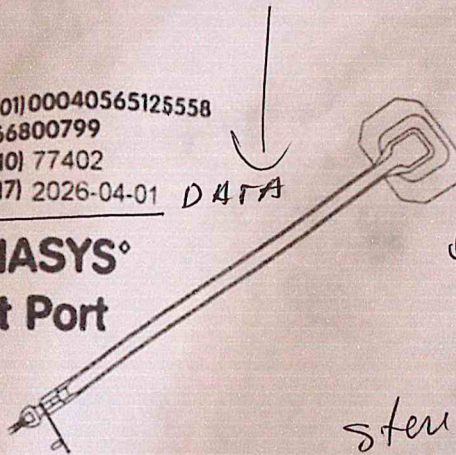
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3. Indications for use

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The RENASYS Y-connector is only intended to be used in conjunction with RENASYS Negative Pressure Wound Therapy (NPWT) system which is indicated for patients who would benefit from a suction pump (Negative

Pressure Wound Therapy), as it may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates and infectious materials.

Appropriate wound types include:

| Wound types | RENASYS Y-connector configuration | |
|---------------------------------------|-----------------------------------|-----------------------------|
| | Single wound | Two wounds of the same type |
| Chronic | ✓ | ✓ |
| Acute | ✓ | ✓ |
| Traumatic | ✓ | ✓ |
| Sub-Acute and dehiscent wounds | ✓ | ✓ |
| Ulcers (such as pressure or diabetic) | ✓ | ✓ |
| Partial-thickness burns | ✓ | ✓ |
| Flaps and grafts | ✓ | ✗ |
| The open abdomen | ✓ | ✗ |

Contraindications ✗ A Y-connector must not be used to connect dressings on different types of wounds.

4. Contraindications

The use of the RENASYS NPWT System 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

5. Warnings

The pump alarms may not sound when a blockage is present in a RENASYS Y-connector branch, so the patient must be monitored more frequently. 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. Do not use a RENASYS Y-connector with breached or damaged packaging. Do not use the RENASYS Y-connector to treat more than two wounds. Do not use more than one Y-connector per pump.

5. Do not connect two wounds of different etiologies (e.g., surgical dehiscence and explored fistula) via the RENASYS Y-connector due to the risk of cross contamination or impaired therapy.
6. Do not use the same RENASYS Y-connector to connect two patients to a single pump.
7. 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.
8. 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.

6. Precautions

As a condition of use, the RENASYS NPWT system should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which the RENASYS Y-connector is being used. 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 wound whenever therapy is active. Monitor the patient for any signs of local or systemic infection. Infected wounds require more frequent monitoring and 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 in the area surrounding the wound, contact the treating clinician immediately. When bathing or moving the patient must disconnect from the RENASYS Y-connector leaving it on the pump. Use the connector caps on the Soft Port/Drain adaptor and Y-connector to avoid leakage of wound fluid. Ensure the aeration disc located on the orange quick click connector is free of moisture before reactivation of therapy to ensure proper alarm

5. functionality and prevent interruption in therapy. RENASYS Y-connector should only be used with Smith & Nephew authorized 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. When a RENASYS Y-connector is used to connect two RENASYS Soft Ports and/or drains to the pump in a two - wound configuration, the blockage alarm may not sound when a blockage is present. The patient should be monitored at least every 4 hours.
9. When a RENASYS Y-connector is used in conjunction with RENASYS AB Abdominal Drainage Port, the Y-connector should be used for single wound therapy.
10. Avoid using RENASYS Y-connector in high pressure settings.
11. The type of dressing kit should be used for two wounds using the RENASYS

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Contraindications

Warnings

A pump alarm may be present in a RENASYS Y-connector. The patient must be monitored more frequently for the patient more frequently when treating open or advancing infections in the area around the pump. If there are any signs of systemic infection, contact the treating clinician immediately. Use a RENASYS Y-connector with breached or damaged packaging. Do not use the RENASYS Y-connector to treat more than one wound. Do not use more than one connector per pump.

Instructions

For proper use, the RENASYS NPWT system must be used by qualified and authorized personnel. The user must have the necessary training for the specific medical application for the RENASYS Y-connector. The RENASYS Y-connector seal may be lost or pooling may occur during activation, when an occlusion forms on the side of the dressing. Viscous, purulent or excessive drainage may contribute to occlusion. Regular monitoring of the pump and dressing removal. Ensure the wound dressing is fully compressed and firm to the skin. If therapy is active. Monitor for any signs of local or systemic infection. Wounds require more frequent dressing changes. If there are any signs of infection or advancing infection in the area around the wound, contact the treating clinician.

When the patient must be moved, the RENASYS Y-connector leaving the connector caps on the Soft and Y-connector to avoid leakage. The aeration disc located near the connector is free of moisture. Therapy to ensure proper

- Do not connect the RENASYS Y-connector to a surgical drain or other medical device. Contamination or impairment of the patient may occur.
- Do not use the same RENASYS Y-connector to connect two patients to a single pump. Care should be taken to ensure the Y-connector does not lie in a position where pressure damage to the patient may occur.
- Do not use the RENASYS Y-connector on wounds if the pump is not used with the Y-connector on one side.
- Do not use the RENASYS Y-connector to prevent internal therapy. Use of the Y-connector should be avoided with other products. Use of the Y-connector with other products may be proven unsafe and ineffective for use with the pump.
- NPWT should remain on for a minimum of 24 hours. The length of time a patient is on NPWT is a clinical decision based on individual characteristics of the patient and factors to consider including location of wound, drainage, integrity of the dressing seal, assessment of bacterial burden and the patient's risk of infection.
- RENASYS Y-connector should be used only once. Use of a single Y-connector for more than one patient may result in cross contamination that may lead to infection.
- When a RENASYS Y-connector is used to connect two RENASYS Soft and/or drains to the pump, the blockage alarm may not sound when a blockage is present. The patient should be monitored at least every 24 hours.
- When a RENASYS Y-connector is used in conjunction with a Soft and/or drain, the Soft and/or drain should only be used on a single patient.
- Avoid connecting the RENASYS Y-connector to connect two patients to a single pump. Use of the Y-connector with other products may be proven unsafe and ineffective for use with the pump.
- The same RENASYS Y-connector should be used with the RENASYS Y-connector.

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