Basic operation

Installing the canister

1. Ensure device is off.
2. Remove paper tape around canister tubing to release tubing to full length.
3. Open both orange clips on sides of canister.
4. Align canister so the viewing window is facing forward.
5. Push canister gently over device inlet port.
6. Engage both orange canister clips. Clips will click when they are properly engaged.

Start up of device

Press and hold POWER ⏻ button for 2 seconds until start up message appears.

Select pressure setting

Use UP and DOWN selectors to adjust.

Start therapy

Press SELECT button to start therapy.

Modes of operation

To change therapy between “Continuous” and “Intermittent” mode:

1. Turn device off.
2. Simultaneously press and hold DOWN + SELECT + POWER buttons for 2 seconds.
3. Press UP ⏶ or DOWN ⏷ selectors to scroll between “Continuous” and “Intermittent” mode. Press SELECT ⏵ button to confirm.
4. Once therapy is started the display screen will show which mode of therapy has been selected.

Check dressing for a good seal

Look for a fully compressed, “raisin-like” appearance.

Listen for a “hissing” sound, indicating a leak.

Feel the dressing, which should be firm to the touch.

Addressing dressing leak

Seal film edges with adhesive gel patch or transparent film. If a hole is found in transparent film, patch with additional transparent film.

Possible sources of leak

- Where Soft Port attaches to film
- Wrinkle or crease
- Skin fold or crevice

Troubleshooting guide

Alarm status with display screen	Cause	Remedy
!! WARNING !! LEAK	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, checkwound dressing for air leaks. Look for loose orde compressed 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. 3. Disconnect Soft Port from canister tubing at orange quick click connectors and insert tethered cap into both connectors. – If alarm condition continues, there is a potential issue with device or canister. Replace canister and contact your Smith+Nephew authorized representative. – If alarm condition resolves, an air leak is present within wound dressing or Soft Port. Reassess and replace as needed.
!! WARNING !! LOW VACCUME	Device is unable to achieve selected vacuum level due to internal device malfunction or a significant leak in the system.	
!! WARNING !! BLOCKAGE/FULL !! Please Return	There is a complete blockage in the 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 max volume (300ml or 750ml fill line), replace canister. 2. Inspect connections, tubing and Soft Port aeration disc (near 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 quick click connector. Allow air to flow freely into canister tubing. – If alarm condition continues, there is a potential issue with device or canister. Replace canister and contact your Smith+Nephew authorized representative. – If alarm condition resolves, a blockage is present within Soft Port. Reassess and replace as needed.
!! DEVICE FAILED !! Please Return !! Please Return	Internal hardware failure.	Contact your local Smith+Nephew representative.

Refer to RENASYS® GO user manual (REF 66021739) for complete troubleshooting guide.

Results

- Patients achieving complete wound closure (primary endpoint) was similar (non-inferior) for GRAFIX PRIME and Dermagraft (Figure)
- For GRAFIX PRIME compared with Dermagraft there were no significant differences in:
  - Wound area reduction ≥50%
  - Number of product applications
  - Mean percentage wound area reduction
- For GRAFIX PRIME compared with Dermagraft in DFUs ≤5cm²:
  - Significantly more patients achieved complete wound closure at the end of treatment (p=0.0118; Figure)
  - Mean per-patient product costs were significantly reduced ($3,846 vs $7,968; p<0.0001)

Questions?

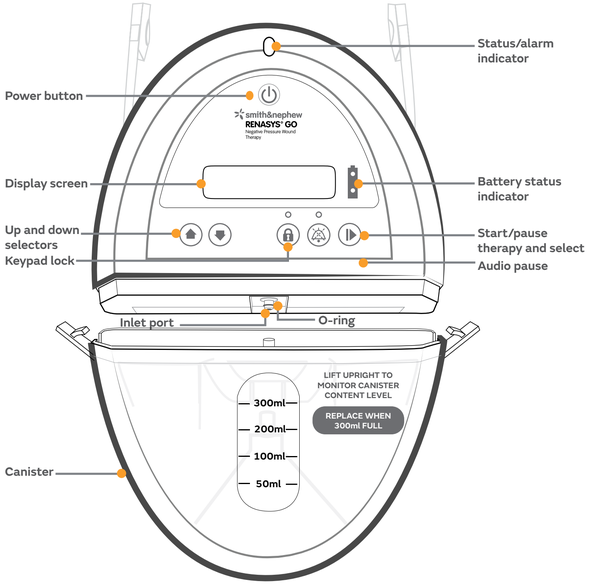
For 24/7 NPWT clinical support, call 1-800-876-1261.

For use with Soft Port

Quick reference guide

Smith+Nephew

RENASYS◊ GO
Negative Pressure Wound Therapy System



Symbols/alarms

Power
Turns device ON and OFF.

Battery status indicator
Shows status of battery life. Illuminates solid yellow when battery life reaches levels that require user intervention.

Up selector
Allows pressure setting to be increased and scroll through menu options.

Down selector
Allows pressure setting to be decreased and scroll through menu options.

Keypad lock
Locks keypad to restrict accidental adjustment of therapy. When lock is activated the light will illuminate solid blue.

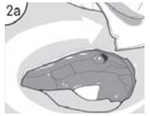
Audio pause
Pauses alarm for approximately 2-3 minutes. When activated the light will illuminate solid yellow.

Start/pause therapy and select
Starts or pauses therapy. It is also used to confirm settings within therapy.

Symbols/alarms Dressing wound – RENASYS°-F foam and -G gauze dressing kits with Soft Port

Dressing application:
Use clean or antiseptic techniques for application according to institutional protocol. Clean wound with each dressing change.

Debride any devitalized necrotic eschar tissue. Cleanse wound bed and pat dry.

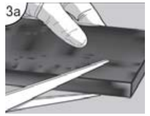


If desired, protect periwound skin from exposure to moisture and adhesive through use of a skin sealant. Allow skin sealant to dry fully prior to placement of transparent film.

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 non-adherent dressing are not included as part of RENASYS-F or RENASYS-G sterile kits.

For foam dressing kits:



Cut foam dressing to fit the size and shape of wound and place into wound cavity. Foam should completely fill wound cavity. Avoid over packing. It may be necessary to stack pieces of foam in deep wounds.

PRECAUTIONS SPECIFIC TO FOAM:
1. Foam should be cut to fit loosely into wound bed. Do not force or tightly pack foam into any areas of wound, to avoid damaging underlying tissue.
2. Do not place foam into blind or unexplored tunnels. If a tunnel of known depth presents, cut foam longer than the tunnel, to ensure direct contact is made with the foam in primary wound cavity.
3. Do not cut foam directly over wound cavity to avoid foam fragments falling into wound. Rub edges of foam, away from the open wound, to remove loose fragments after cutting.
4. If multiple pieces of wound filler are needed to fill wound profile, count and record how many pieces are present to ensure all pieces are removed at dressing change to minimize risk of retention and possible infection.

For gauze dressing kits:

Apply a layer of saline moistened antimicrobial gauze to wound bed. Unfold remaining saline-moistened gauze and loosely fill entire wound cavity. Avoid overpacking wound.

Note: Saline not included in RENASYS-G sterile kit.

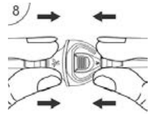
PRECAUTIONS SPECIFIC TO GAUZE:
1. Use of gauze as a filler in wounds that are in a weight bearing location or have moderate to heavy drainage may challenge the transfer of fluid and vacuum. Foam is recommended in these wounds.
2. If multiple pieces of wound filler are needed to fill wound profile, count and record how many pieces are present to ensure all pieces are removed at dressing change to minimize risk of retention and possible infection.

Cover wound filler with transparent film. Film should extend 5cm/ 1.97in beyond wound margin to facilitate adequate seal.
Film should be securely anchored to periwound area to maintain a good seal.

Cut a circular hole (no less than 2.0cm/0.97in) in the center of film, over wound filler. Remove excess trimmed film and dispose of away from wound.

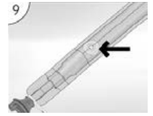
Remove liner from the Soft Port dressing. Align port opening directly over hole in the transparent film.

Use gentle pressure to anchor Soft Port dressing to the transparent film. Smooth the dressing down while removing the Soft Port's top stabilization frame.



Attach the Soft Port tubing to the canister tubing, activate the device and adjust to the prescribed therapy level. The recommended therapeutic pressure range is 40-120mmhg.

Finished dressings should be leak-free, fully compressed and firm to the touch.



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

Dressing changes

RENASYS° foam dressings should be changed every 48 to 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.
RENASYS 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.

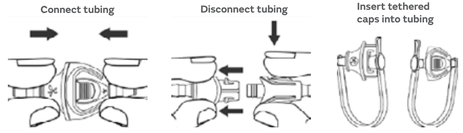
Canister selection

The RENASYS GO device can only be used with the 300ml canister kit (REF 66020914) or 750ml canister kit (REF 66020916).

The canister 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 (300ml or 750ml fill line). Canisters may have to be changed regularly within singlepatient treatment episodes if exudate levels are high. Do not wait for alarm activation to change canister.

Canisters are provided non-sterile and should not be used in a sterile field.

Canister tubing



Notes:

- Please refer to the RENASYS GO user manual for a complete discussion of indications, contraindications, precautions, warnings, and manufacturer's recommendations.
- Please refer to the RENASYS-F foam dressing kit with Soft Port and RENASYS-G gauze dressing kit with Soft Port instructions for use for full application techniques.
- Use clean or sterile/aseptic techniques for application depending on institutional protocol.
- Only the Smith+Nephew wound dressing kits, canisters and ancillary components are approved for use with RENASYS GO.
- RENASYS high output dressing kit (REF 66800932) is not compatible with
- RENASYS GO due to tubing configuration.