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URGENT: MEDICAL DEVICE CORRECTION NOTICE

RENASYS® EZ/RENASYS EZ Plus Canister Component of RENASYS EZ and RENASYS EZ Plus Negative Pressure Wound Therapy Systems

Product code	Product description
• 66800912	RENASYS EZ/RENASYS EZ Plus 800 ml Canister with Solidifier
• 66800913	RENASYS EZ/RENASYS EZ Plus 250 ml Canister with Solidifier
• 66801066	RENASYS EZ/RENASYS EZ Plus 800 ml Canister without Solidifier
• 66800423	RENASYS EZ/RENASYS EZ Plus 800ml Canister with Solidifier
• 66800058	RENASYS EZ/RENASYS EZ Plus 250ml Canister with Solidifier

Smith & Nephew is providing this notice to advise users of its RENASYS EZ and RENASYS EZ Plus Negative Pressure Systems of a design modification to the bacterial overflow guard (filter) to reduce the potential of introducing air leakage in the vacuum circuit during system set-up and operation.

No removal of product distributed to the market is required and all canisters and bacterial overflow guards supplied by Smith & Nephew for use with RENASYS EZ/RENASYS EZ Plus systems can be used safely if they are used in accordance with the instructions in the supplied user manual.

A modification has been implemented to the bacterial overflow guard (filter) on all canisters made in October 2013 or later. The bacterial overflow guard (filter) assembly is supplied from the factory attached to the canister. Lot numbers for all product codes are assigned sequentially. Lot numbers that are lower than M400300 were manufactured with the original bacterial overflow guard (filter) subject to this notice.

Indications for use

RENASYS◊ EZ/RENASYS EZ Plus is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy), as it may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates and infectious materials.

Examples of appropriate wound types include:

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

Dear valued customer,

The Product Codes listed on the previous page are exudate collection Canisters used in conjunction with RENASYS EZ and RENASYS EZ Plus Negative Pressure Wound Therapy (NPWT) Systems. The Canister assemblies consist of a collection canister, canister lid, tubing and a factory attached bacterial overflow guard (filter) intended to be connected to the pump by the user. A material change to the bacterial overflow guard (filter) has been implemented to ensure it can be more easily and reliably connected to the pump by the user.

Smith & Nephew, Inc. is aware of reports from users of its RENASYS EZ and RENASYS EZ Plus Negative Pressure Wound Therapy Systems of cases in which wound fluid and/or blood was not evacuated from beneath the wound dressing and the pump blockage alarm did not activate. Information obtained from these reports and follow-up investigations confirm that air leakage is a contributing factor in such occurrences. Removal of all sources of air leaks within Negative Pressure Wound Therapy systems is essential to allow the devices to function as intended Review of the overall operation of the RENASYS EZ and RENASYS EZ Plus Negative Pressure Wound Therapy Systems identified a potential source of air leakage at the point of connection of the bacterial overflow guard (filter) with the pump due to incomplete insertion.

Failure to evacuate wound fluid and/or blood from beneath the wound dressing and pump blockage alarm failure due to unintended air leakage may result in an increased health risk of wound maceration, local or systemic infection. There have been six reports of serious injury received citing wound fluid and or blood pooling beneath the dressing and non-activation of the blockage alarm that may have been associated with unintended air leakage in the system. Smith & Nephew's risk

assessment concluded the frequency of such adverse events potentially due to this failure mode is low.

In order to reduce the likelihood of air leakage at this point, a change to the design of the bacterial overflow guard (filter) has been implemented by Smith & Nephew, to both help ensure that the bacterial overflow guard (filter) can be more easily and reliably inserted into the vacuum port on the front of the pump and to help the user recognize when the bacterial overflow guard is properly seated at the point of connection. The design change consists of a change to the material of the bacterial overflow guard (filter) housing to use a more pliable (softer) material. The material change improves the user's ability to recognize when complete insertion of the bacterial overflow guard (filer) into the pump vacuum port is achieved. The bacterial overflow guard (filter) component comes to a 'hard stop' when fully inserted to fourth ridge as described in the user instructions.

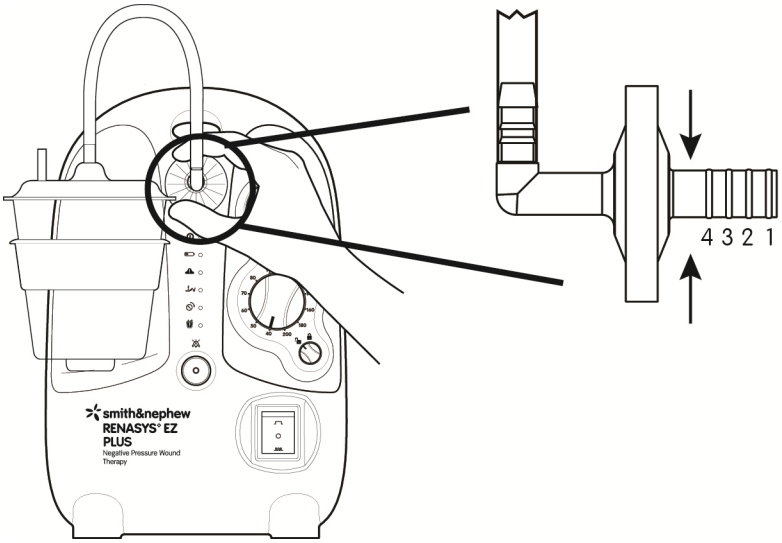
Users are reminded, in all cases, to apply the following to ensure safe and effective operation of RENASYS® EZ and RENASYS EZ Plus Negative Pressure Systems:

- Carefully follow the correct system set-up instructions contained in the user manual and ensure the bacterial overflow guard is fully inserted. Refer to the instructions on the next page for proper canister connection.
- Note that alarms and system displays are not intended to replace physical inspection and monitoring of system operation by health care providers. Assure that the patient is monitored at a frequency appropriate to the care setting by a trained practitioner. In determining the frequency of monitoring, consider the patient's condition, including the wound status, wound location and co-morbidities. Ensure consistent wound care management by following the patient's care plan.
- **How to recognize that the device alarm may fail:**
  1. Ensure that the bacterial overflow guard (filter) component comes to a 'hard stop' when fully inserted past the fourth ridge as described in the user instructions.
  2. To verify functional blockage alarm 'cap off' the canister tubing at the connector to simulate a blockage and activate the blockage alarm.

INSTRUCTIONS TO USERS

Installing the RENASYS® EZ/RENASYS EZ Plus Canister

1. Ensure the vacuum is turned off.
2. Connect the blue end of the canister tubing to the canister lid port labeled with the patient symbol:
3. **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.



Note: Inserting the bacterial overflow guard completely may require force.

4. Securely connect the opposite end of the canister tubing to the wound dressing tubing.

Additional consultation regarding the safe and effective use of RENASYS EZ and RENASYS EZ Plus Negative Pressure Wound Therapy (NPWT) Systems or assistance with the clinical set-up and operation of the system please contact the Smith & Nephew Clinical Hotline at:

866-998-6798

To schedule additional training for clinical staff please contact your local Smith & Nephew Advanced Wound Management representative.

Device users are reminded that reports of adverse events experienced with medical devices should be reported to FDA's MedWatch Adverse Event Reporting program. Reports may be made online, by fax or by mail. Information regarding the MedWatch program and reporting instructions are available on FDA's website at http://www.fda.gov/MedicalDevices/default.htm

For questions or additional information please contact Terry McMahon, Director of Regulatory Affairs and Quality, North America at 727-399-3785 or terry.mcmahon@smith-nephew.com.

Sincerely yours,

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Advanced Wound Management