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We are smith&nephew

07 October, 2014

Customer Name
Device Name
Street Address
City, State, Zip Code

PLEASE NOTE: THIS NOTIFICATION IS AN ADDITION TO THE FIELD SAFETY NOTICE DISPATCHED ON 01 OCTOBER

URGENT: EXTENDED FIELD SAFETY NOTICE
RENASYS™ EZ, RENASYS™ EZ PLUS, RENASYS™ GO

Dear Device Customer/Distributor,

After further investigation, we have determined that two additional Renasys product codes are affected by the corrections identified in the Field Safety Notice of 01 October 2014.
These are :

66800946 - 800 ML – S CANISTER KIT
66800961 - Renasys-G Sterile, Gauze Dressing Kit with SoftPort

We are therefore re-issuing the full Field Safety Notice to include the additional two codes. We apologise sincerely for any inconvenience this may have caused you or your organisation.

Following discussions with various Competent Authorities in the EU and a recent review of post marketing surveillance information regarding our RENASYS™ ® range of Negative Pressure Wound Therapy ("NPWT") devices ('RENASYS™ devices), Smith & Nephew are issuing a Field Safety Notice ('FSN') concerning RENASYS™ devices. The purpose of the FSN is:

1. To inform users of changes that have been implemented on RENASYS™ devices and to instruct users to discard certain RENASYS™ consumables.

2. To announce the implementation of amended Instructions For Use ('IFU') for RENASYS™ devices, to remind customers of the importance of patient monitoring requirements during negative pressure wound therapy.

This FSN has been agreed by relevant Competent Authorities in the EU.

1. Product Changes

Smith & Nephew implemented a number of changes to RENASYS™ devices on the basis of customer feedback ('the changes'). Table 1 below sets out:

- Descriptions of the product changes,
- The rationale for the product changes,
- The Customer action required

TABLE 1

<table>
<tr><th>Applicable RENASYS™ System</th><th>Description of Product Change</th><th>Rationale for the Product Change</th><th>Customer action</th></tr>
<tr><td>EZ / EZ Plus</td><td>Bacterial Overflow Guard material change</td><td>The material was changed to allow easier insertion to the RENASYS EZ / EZ Plus devices</td><td>In the event that users still have RENASYS™ devices with lot numbers that pre-date the changes in inventory (the detailed lot numbers affected are set out below), further action is required: more specifically, users are required to discard any Canisters Kits remaining in their inventory
<table>
<tr><th>Product Description / Product Code</th><th>Affected Lot Numbers</th></tr>
<tr><td>RENASYS™ EZ Plus Canister 800ml with solidifier / 66800912</td><td>All lots < M400300</td></tr>
<tr><td>RENASYS™ EZ Plus Canister 250ml with solidifier / 66800913</td><td>All lots < M400300</td></tr>
<tr><td>RENASYS™ EZ Plus Canister 800ml with without solidifier / 66801066</td><td>All lots < M400300</td></tr>
<tr><td>RENASYS™ EZ Plus Canister 800ml with solidifier / 66800423</td><td>All lots < M400300</td></tr>
<tr><td>RENASYS™ EZ Plus Canister 250ml with solidifier / 66800058</td><td>All lots < M400300</td></tr>
<tr><td>800 ML – S CANISTER KIT / 66800946</td><td>All lots < M400300</td></tr>
</table>
For ease of identification of affected lots for the RENASYS EZ Plus Canisters:
The lot number follows a sequential numbering system, with the letter bearing no factor on this seqence. Therefore all lots with a number lower than M400300 are affected.</td></tr>
</table>

<table>
<tr>
<td>All RENASYS™ Systems</td>
<td>Soft Port Aperture change</td>
<td>Size of the aperture was changed in order to:
(i) allow easier alignment of the Soft Port and the hole cut in the transparent film;
(ii) improve the management of viscous fluid</td>
<td>In the event that users still have RENASYS™ devices with lot numbers that pre-date the changes in inventory (the detailed lot numbers affected are set out below), further action is required: more specifically, users are required to discard any Soft Ports Kits remaining in their inventory.
<table>
<tr><th>Product Description / Product Code</th><th>Affected Lot Numbers</th></tr>
<tr><td>RENASYS™ -F Small with Soft Port / 66800794</td><td>All lots < 2013011828</td></tr>
<tr><td>RENASYS™ -F Medium with Soft Port / 66800795</td><td>All lots < 2013010125</td></tr>
<tr><td>RENASYS™ -F Large with Soft Port / 66800796</td><td>All lots < 2013011692</td></tr>
<tr><td>RENASYS™ -F Extra Large with Soft Port / 66800797</td><td>All lots < 2013011830</td></tr>
<tr><td>RENASYS™ Soft Port Kit / 66800799</td><td>All lots < 2013010311</td></tr>
<tr><td>Abdominal Kit / 66800980</td><td>All lots < 2013010287</td></tr>
<tr><td>RENASYS™ -G Small with Soft Port / 66800933</td><td>All lots < 2013020417</td></tr>
<tr><td>RENASYS™ -G Medium with Soft Port / 66800934</td><td>All lots < 2013020209</td></tr>
<tr><td>RENASYS™ -G Large with Soft Port / 66800935</td><td>All lots < 2013020382</td></tr>
<tr><td>RENASYS™ -G Extra Large with Soft Port / 66800936</td><td>All lots < 2013020501</td></tr>
<tr><td>Renasys-G Sterile, Gauze Dressing Kit with SoftPort / 66800961</td><td>All lots < 2013020740</td></tr>
</table>
For ease of identification of affected Soft Port Kits, the following text explains how the lot number is structured:
E.g. Lot number 2013010287 → [2013] [01] [02] [87]
The digits in the first bracket denotes the year of manufacturer: 2013
The digits in the second bracket denotes the Month: January
The digits in the third bracket denotes the day of the Month: 2nd
The digits in the fourth bracket denotes the sequential batch number: 87th batch produced</td>
</tr>
</table>

<table>
<tr>
<td>All RENASYS™ systems</td>
<td>Soft Port backing paper slit addition</td>
<td>To allow easier application of the Soft Port dressing</td>
<td>In the event that users still have RENASYS™ devices with lot numbers that pre-date the changes in inventory (the detailed lot numbers affected are set out below), further action is required: more specifically, users are required to discard any Soft Ports Kits remaining in their inventory.
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<tr><td>RENASYS™ -F Large with Soft Port / 66800796</td><td>All lots < 2013011692</td></tr>
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The digits in the first bracket denotes the year of manufacturer: 2013
The digits in the second bracket denotes the Month: January
The digits in the third bracket denotes the day of the Month: 2nd
The digits in the fourth bracket denotes the sequential batch number: 87th batch produce</td>
</tr>
</table>

<table>
<tr>
<td>RENASYS™ EZ / EZ Plus</td>
<td>800ml canisters</td>
<td>The PVC tubing material was changed to prevent the deformation of the canister inlet port</td>
<td>In the event that users still have RENASYS™ devices with lot numbers that pre-date the changes in inventory (the detailed lot numbers affected are set out below), further action is required: more specifically, users are required to discard any Canisters Kits remaining in their inventory
<table>
<tr><th>Product Description / Product Code</th><th>Affected Lot Numbers</th></tr>
<tr><td>RENASYS™ EZ Plus Canister 800ml / 66800912</td><td>All lots < M400140</td></tr>
<tr><td>RENASYS™ EZ Plus Canister 800ml without solidifier / 66801066</td><td>All lots < M400140</td></tr>
<tr><td>RENASYS™ EZ Plus Canister 800ml / 66800423</td><td>All lots < M400140</td></tr>
<tr><td>800 ML – S CANISTER KIT / 66800946</td><td>All lots < M400140</td></tr>
</table>
For ease of identification of affected lots for the RENASYS EZ Plus Canister 800ml.

The lot number follows a sequential numbering system, with the letter bearing no factor on this seqence. Therefore all lots with a number lower than M400140 are affected.</td>
</tr>
</table>

2. <u>Amendments to the IFU</u>

Smith & Nephew hereby announces changes to the IFU for the RENASYS™ devices listed in Table 2.

TABLE 2

Product Codes	**Product Description**
66800164, 66801244, 66801496	RENASYS™ GO
66800059	RENASYS™ EZ
66800697, 66801243	RENASYS™ EZ PLUS
66801309, 66801310	RENASYS™ EZ MAX

Smith & Nephew has become aware of cases where a blockage can occur beneath the RENASYS™ devices film dressing, reducing fluid removal from the dressing through the port and into the canister. Notably, heavy wound exudate, viscous wound exudate, exudate with sediment or when blood is present can lead to the saturation of the wound filler, and to blockage formation. This situation can arise with both gauze and foam wound fillers.

If a blockage occurs in this way, the exudate may accumulate or "pool" beneath the film dressing, which creates a potential risk of maceration to surrounding tissue and can eventually, cause the dressing to lift and allow exudate to leak from the wound.

Smith & Nephew determined that RENASYS™ devices may not be able to detect such blockages if the vacuum between the pump and the dressing is still present. In these circumstances, RENASYS™ devices may not alarm to alert the user to the presence of the blockage.

Even in cases where the dressing has visibly lifted, it is still possible that the device may not alarm, as a vacuum is still being maintained between the dressing, the port and the device.

On the basis of these observations, Smith & Nephew will amend the IFUs applicable for the RENASYS™ ® range of products, to re-emphasise the importance of patient monitoring requirements. The IFU amendments will remind customers that the dressing is to be checked regularly to ensure that pooling is not occurring beneath the dressing and remind users not to rely solely on the device alarms to ensure that therapy is being effectively delivered.

Smith & Nephew expects that the revised instructions will be available for all users by the **30th November, 2014**. In the interim, this letter will provide you with the essential elements of the revised IFU as soon as possible.

Please note that you are required to complete and return the attached *Acknowledgement and Receipt Form* by [date], **even if you do not have any product on hand.**

Should you have any questions in relation to this FSN including product replacements, please do not hesitate in contacting Smith & Nephew via email Advice.Healthcare@smith-nephew.com or telephone UK (0800) 9155 394, IRE (1800) 30 36 22.

The revised IFU will include the following “Important information” section:

Important information
Monitoring NPWT

Carefully monitor the patient, device and dressing frequently, to determine if there are any signs of bleeding, exudate accumulation (pooling), infection, maceration, or loss of Negative Pressure Wound Therapy (NPWT). The frequency should be determined by the clinician based on individual characteristics of the patient and wound. NPWT devices 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 system 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 fluid removal or occlusion formation. A full canister, incorrect canister orientation and device/tubing height relative to the wound can contribute to loss of NPWT and exudate accumulation within the wound, which could lead to maceration, infection, or unrecognised bleeding.

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 NPWT is being delivered.

The revised IFU will also include the following “Cautions” for leak alarms and blockage alarms:

Caution – Lack of Blockage alarm:

If partial blockage occurs, the change in pressure status detected by device may not be significant enough to trigger alarm activation. Over time if blockage reaches point of full occlusion, complete blockage alarm will activate.

Blockage formation within the wound dressing will not be detected by the system as it has occurred outside of the monitored vacuum circuit, but can affect pressure status at the wound. Appropriately frequent monitoring of wound dressing is recommended to confirm adequate delivery of therapy.

In the event of heavy or viscous drainage, drainage with sediment or when blood is present, regular monitoring and more frequent dressing changes may be required.

If a complete blockage is present in the system, but an air leak occurs between blockage and device, the alarm may not activate. Ensure all connections are secure and no air leaks are present in system.

Potential sources of air leaks include:

- Misplaced or worn O-ring on the RENASYS GO device inlet port, located between the device and canister
- Partially inserted in-line bacterial overflow guard on the RENASYS EZ/EZ PLUS/EZ MAX devices
- Tear in Soft Port
- Misplaced or worn O-ring within the quick click connector (between the Soft Port and canister tubing)
- Cracked or damaged canister

Caution – Lack of Leak alarm:

Under specific circumstances, a significant air leak may occur in system without device activating a high flow/leak alarm. This may be due to partial blockage between source of air leak and device, prohibiting detection of the leak by device, resulting in no alarm activation.

Potential sources of blockage include:

- Physical occlusion in wound dressing (coagulated blood or purulent material in filler, compacted filler, high volume viscous fluid)
- Physical occlusion in tubing (kink in canister tubing, clot in tubing)
- Soft Port aperture misaligned to dressing opening.

Check wound dressing regularly to ensure it is fully compressed and firm to the touch.

STEPS FOR FIELD SAFETY NOTICE

The *Acknowledgement, Receipt and Confirmation of Disposal Form* attached to this letter must be completed and returned even if you do not have any product in your inventory.

THIS FIELD SAFETY NOTICE DOES NOT REQUIRE ANY RETURN OF RENASYS™ NPWT PRODUCTS.

THIS FIELD SAFETY NOTICE REQUIRES CUSTOMERS TO DISCARD AFFECTED RENASYS™ NPWT PRODUCTS

DO NOT DISCONTINUE TREATMENT OR RETURN ANY PRODUCT

1. **Identify users of RENASYS™ NPWT systems**. Please identify all users of Smith & Nephew RENASYS™ range of NPWT systems, who may need to be made aware of the enhancements to the IFU and Product changes contained in this Field Safety Corrective Action. Users may be healthcare professionals, home care workers or patients.
2. **Provide copies of this notice to all identified users as soon as is reasonably practicable.**
3. **Complete the *Acknowledgement, Receipt and Confirmation of Disposal Form*.** Complete and return the enclosed ***Acknowledgement, Receipt and Confirmation of Disposal Form*** as soon as reasonably possible. If necessary, your Smith & Nephew sales representative can assist you in completing the form.
4. Please return the completed form via email Advice.Healthcare@smith-nephew.com , F: 44(0) 1482 222 211, or by post using the pre-paid envelope provided.

Approved By:

David Wright
Regulatory & Quality Manager
Advanced Wound Care, UK & Ireland

We are smith&nephew

Updated 10/10/2014

IMPORTANT - MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE

Acknowledgement, Receipt and Confirmation of Disposal Form

Response is required within 15 days

Customer Information:
Customer Name
Street Address
Town, State, Zip Code

RENASYS™ EZ, RENASYS™ EZ PLUS, RENASYS™ EZ MAX, RENASYS™ GO

I have read and understood the information contained in this letter and have distributed copies to all relevant users, as defined in the instructions.

PLEASE SELECT THE APPROPRIATE OPTION IN TABLE A

Table A

I have checked inventory for the affected products listed in the Field Safety Notice and confirm zero inventory remaining	☐
I have checked inventory for the affected products listed in the Field Safety Notice and can confirm inventory remaining [IF YOU TICK THIS BOX PLEASE ALSO COMPLETE TABLE B]	☐

Table B - ONLY COMPLETE THIS TABLE IF YOU HAVE IDENTIFIED AFFECTED PRODUCTS LISTED IN THE FIELD SAFETY NOTICE IN YOUR LOCATION

Product description	Lot number	Quantity of product discarded

[ADD ADDITIONAL ROWS IF REQUIRED]

Please provide any additional information, if applicable.

Name	
Signature	
Title	
Telephone	
Email address	

2. PLEASE EMAIL, FAX or POST the COMPLETED RESPONSE FORM TO: Advice.Healthcare@smith-nephew.com , F: 44(0) 1482 222 211, or post using the pre-paid envelope provided.