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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™<sup>®</sup> 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**

Applicable RENASYS™ System	Description of Product Change	Rationale for the Product Change	Customer action														
EZ / EZ Plus	Bacterial Overflow Guard material change	The material was changed to allow easier insertion to the RENASYS EZ / EZ Plus devices	<p>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</p> <table border="1" data-bbox="652 991 1414 1430"> <thead> <tr> <th data-bbox="659 999 1130 1026">Product Description / Product Code</th> <th data-bbox="1133 999 1408 1026">Affected Lot Numbers</th> </tr> </thead> <tbody> <tr> <td data-bbox="659 1035 1130 1100">RENASYS™ EZ Plus Canister 800ml with solidifier / 66800912</td> <td data-bbox="1133 1035 1408 1100">All lots &lt; M400300</td> </tr> <tr> <td data-bbox="659 1108 1130 1173">RENASYS™ EZ Plus Canister 250ml with solidifier / 66800913</td> <td data-bbox="1133 1108 1408 1173">All lots &lt; M400300</td> </tr> <tr> <td data-bbox="659 1182 1130 1247">RENASYS™ EZ Plus Canister 800ml with without solidifier / 66801066</td> <td data-bbox="1133 1182 1408 1247">All lots &lt; M400300</td> </tr> <tr> <td data-bbox="659 1255 1130 1320">RENASYS™ EZ Plus Canister 800ml with solidifier / 66800423</td> <td data-bbox="1133 1255 1408 1320">All lots &lt; M400300</td> </tr> <tr> <td data-bbox="659 1329 1130 1394">RENASYS™ EZ Plus Canister 250ml with solidifier / 66800058</td> <td data-bbox="1133 1329 1408 1394">All lots &lt; M400300</td> </tr> <tr> <td data-bbox="659 1402 1130 1430">800 ML – S CANISTER KIT / 66800946</td> <td data-bbox="1133 1402 1408 1430">All lots &lt; M400300</td> </tr> </tbody> </table> <p>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 sequence. Therefore all lots with a number lower than M400300 are affected.</p>	Product Description / Product Code	Affected Lot Numbers	RENASYS™ EZ Plus Canister 800ml with solidifier / 66800912	All lots < M400300	RENASYS™ EZ Plus Canister 250ml with solidifier / 66800913	All lots < M400300	RENASYS™ EZ Plus Canister 800ml with without solidifier / 66801066	All lots < M400300	RENASYS™ EZ Plus Canister 800ml with solidifier / 66800423	All lots < M400300	RENASYS™ EZ Plus Canister 250ml with solidifier / 66800058	All lots < M400300	800 ML – S CANISTER KIT / 66800946	All lots < M400300
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800 ML – S CANISTER KIT / 66800946	All lots < M400300																

All RENASYS™ Systems	Soft Port Aperture change	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	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.	
			Product Description / Product Code	Affected Lot Numbers
			RENASYS™ -F Small with Soft Port / 66800794	All lots < 2013011828
			RENASYS™ -F Medium with Soft Port / 66800795	All lots < 2013010125
			RENASYS™ -F Large with Soft Port / 66800796	All lots < 2013011692
			RENASYS™ -F Extra Large with Soft Port / 66800797	All lots < 2013011830
			RENASYS™ Soft Port Kit / 66800799	All lots < 2013010311
			Abdominal Kit / 66800980	All lots < 2013010287
			RENASYS™ -G Small with Soft Port / 66800933	All lots < 2013020417
			RENASYS™ -G Medium with Soft Port / 66800934	All lots < 2013020209
			RENASYS™ -G Large with Soft Port / 66800935	All lots < 2013020382
			RENASYS™ -G Extra Large with Soft Port / 66800936	All lots < 2013020501
			Renasys-G Sterile, Gauze Dressing Kit with SoftPort / 66800961	All lots < 2013020740
			<p>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: 2<sup>nd</sup>            The digits in the fourth bracket denotes the sequential batch number: 87<sup>th</sup> batch produced</p>	

All RENASYS™ systems	Soft Port backing paper slit addition	To allow easier application of the Soft Port dressing	<p>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.</p> <table border="1" data-bbox="691 443 1422 1312"> <thead> <tr> <th data-bbox="691 443 1073 514">Product Description / Product Code</th> <th data-bbox="1073 443 1422 514">Affected Lot Numbers</th> </tr> </thead> <tbody> <tr> <td data-bbox="691 514 1073 585">RENASYS™ -F Small with Soft Port / 66800794</td> <td data-bbox="1073 514 1422 585">All lots &lt; 2013011828</td> </tr> <tr> <td data-bbox="691 585 1073 657">RENASYS™ -F Medium with Soft Port / 66800795</td> <td data-bbox="1073 585 1422 657">All lots &lt; 2013010125</td> </tr> <tr> <td data-bbox="691 657 1073 728">RENASYS™ -F Large with Soft Port / 66800796</td> <td data-bbox="1073 657 1422 728">All lots &lt; 2013011692</td> </tr> <tr> <td data-bbox="691 728 1073 800">RENASYS™ -F Extra Large with Soft Port / 66800797</td> <td data-bbox="1073 728 1422 800">All lots &lt; 2013011830</td> </tr> <tr> <td data-bbox="691 800 1073 871">RENASYS™ Soft Port Kit / 66800799</td> <td data-bbox="1073 800 1422 871">All lots &lt; 2013010311</td> </tr> <tr> <td data-bbox="691 871 1073 911">Abdominal Kit / 66800980</td> <td data-bbox="1073 871 1422 911">All lots &lt; 2013010287</td> </tr> <tr> <td data-bbox="691 911 1073 982">RENASYS™ -G Small with Soft Port / 66800933</td> <td data-bbox="1073 911 1422 982">All lots &lt; 2013020417</td> </tr> <tr> <td data-bbox="691 982 1073 1054">RENASYS™ -G Medium with Soft Port / 66800934</td> <td data-bbox="1073 982 1422 1054">All lots &lt; 2013020209</td> </tr> <tr> <td data-bbox="691 1054 1073 1125">RENASYS™ -G Large with Soft Port / 66800935</td> <td data-bbox="1073 1054 1422 1125">All lots &lt; 2013020382</td> </tr> <tr> <td data-bbox="691 1125 1073 1197">RENASYS™ -G Extra Large with Soft Port / 66800936</td> <td data-bbox="1073 1125 1422 1197">All lots &lt; 2013020501</td> </tr> <tr> <td data-bbox="691 1197 1073 1312">Renasys-G Sterile, Gauze Dressing Kit with SoftPort / 66800961</td> <td data-bbox="1073 1197 1422 1312">All lots &lt; 2013020740</td> </tr> </tbody> </table> <p data-bbox="691 1354 1422 1816">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: 2<sup>nd</sup>  The digits in the fourth bracket denotes the sequential batch number: 87<sup>th</sup> batch produce</p>	Product Description / Product Code	Affected Lot Numbers	RENASYS™ -F Small with Soft Port / 66800794	All lots < 2013011828	RENASYS™ -F Medium with Soft Port / 66800795	All lots < 2013010125	RENASYS™ -F Large with Soft Port / 66800796	All lots < 2013011692	RENASYS™ -F Extra Large with Soft Port / 66800797	All lots < 2013011830	RENASYS™ Soft Port Kit / 66800799	All lots < 2013010311	Abdominal Kit / 66800980	All lots < 2013010287	RENASYS™ -G Small with Soft Port / 66800933	All lots < 2013020417	RENASYS™ -G Medium with Soft Port / 66800934	All lots < 2013020209	RENASYS™ -G Large with Soft Port / 66800935	All lots < 2013020382	RENASYS™ -G Extra Large with Soft Port / 66800936	All lots < 2013020501	Renasys-G Sterile, Gauze Dressing Kit with SoftPort / 66800961	All lots < 2013020740
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RENASYS™ EZ / EZ Plus	800ml canisters	The PVC tubing material was changed to prevent the deformation of the canister inlet port	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	
			Product Description / Product Code	Affected Lot Numbers
			RENASYS™ EZ Plus Canister 800ml / 66800912	All lots < M400140
			RENASYS™ EZ Plus Canister 800ml without solidifier / 66801066	All lots < M400140
			RENASYS™ EZ Plus Canister 800ml / 66800423	All lots < M400140
			800 ML – S CANISTER KIT / 66800946	All lots < M400140
			<p>For ease of identification of affected lots for the RENASYS EZ Plus Canister 800ml.</p> <p>The lot number follows a sequential numbering system, with the letter bearing no factor on this sequence. Therefore all lots with a number lower than M400140 are affected.</p>	

**2. Amendments to the IFU**

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™<sup>®</sup> 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](mailto: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](mailto: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

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	<input type="checkbox"/>
I have checked inventory for the affected products listed in the Field Safety Notice and can confirm inventory remaining	<input type="checkbox"/>
<b>[IF YOU TICK THIS BOX PLEASE ALSO COMPLETE TABLE B]</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	

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