15th December, 2010

URGENT DEVICE RECALL

RE: Product Name: **Renasys Port**
Product Code Number: **66800694**

Dear Customer,

Smith & Nephew, Inc. Wound Management (S&N) is recalling the lots identified below in table 1 of RENASYS Port. It has been determined that there are small holes in the primary pouch which constitutes a breach of the sterile barrier.

Please note this recall is specific only to the Product code: 66800694 and lots listed below. No Renasys Negative Pressure Wound Therapy (NPWT) dressing kits are included in this action.

The affected lots were distributed from April 12, 2010 through November 23, 2010.

Table 1

Product #	Lot #	Product #	Lot #
66800694	50512962	66800694	50539646
66800694	50512969	66800694	50539647
66800694	50512974	66800694	50539648
66800694	50513073	66800694	50546339
66800694	50513074	66800694	50546340
66800694	50513087	66800694	50548244
66800694	50514672	66800694	50548245
66800694	50516110	66800694	50548246
66800694	50517647	66800694	50548247
66800694	50539644	66800694	50548248
66800694	50539645		

The purpose of this letter is to help you with customer correspondence and ensure that we follow the recall process as per company and national guidelines.

Action required by you:

1. Please check your own inventory immediately to identify and quarantine RENASYS PORT from the affected list. Arrange for the affected items to be returned to the Movianto distribution centre in accordance with the instructions below. Please send a scanned / e-mail summary of the identified stock to Robert Whitham (contact details below) to allow global reconciliation of customer returns.

2. Please contact all customers who may have received any of the affected batches listed above, request them to notify you by fax of any affected product which they possess. The attached customer letter and form should be used as the basis of any correspondence. The letter should be amended where indicated (as highlighted) and any special instructions necessary for your market inserted as appropriate.

3. Following receipt of fax notification from the customer to you, please arrange with the customer for the product to be returned directly to the Movianto distribution centre, in accordance with the instructions below. This will obviate the need for you to handle or store any of the affected product. All returned product will be stored by Movianto prior to reconciliation and destruction.

   Please make as many attempts as necessary to obtain this information.

4. Please send a scanned copy of each returned customer fax to Robert Whitham to allow global reconciliation of customer returns

5. If necessary, please notify your local regulatory agency of the recall, in accordance with your national regulatory requirements. The basic information relating to the recall is contained in the attached US FDA notification prepared by the legal manufacturer. Information relating to update notices or closure notices will be provided as the recall progresses, or contact Robert Whitham for additional information. Please copy Robert Whitham on any recall correspondence with the national regulatory agencies.

Replacement Product; Local Customer Care / Marketing groups will be responsible for managing inventory and adjustments with customers.

Product Return: Please supply / use the attached customer return instructions on all product being returned to Movianto, whether from customers or S&N Group companies. This will ensure that returned product is segregated for disposal and not accidentally returned to stock.


Customer Return Label.doc

Please contact Jackie Flynn (contact details below) regarding any questions related to the return of the product to Movianto.

Contacts: If you have any questions concerning this notification or any questions in general, please contact:

Robert Whitham: Outsource Operations QA Manager +44 1482 673267
mailto:robert.whitham@smith-nephew.com

Nina Palmer: Outsourced Operations QA Officer +44 1482 673244
mailto:nina.palmer@smith-nephew.com

Jackie Flynn : Head of Global Logistics +44 1482 673294
mailto:jackie.flynn@smith-nephew.com

Thank you for your help

Yours Sincerely,

Robert Whitham

December 15, 2010

URGENT DEVICE RECALL

ATTENTION: Purchasing
Company Name
Address
City,
Country

RE: Product Name: RENASYS Port
Product Code Number 66800694

Dear Customer,

In order for Smith & Nephew to conduct and document the recall of RENASYS Port, we require completion of this form. We are asking that you take a moment to complete the information requested at the bottom of this letter and promptly return it to us in the business reply envelope provided. Additionally, we ask that you fax your response to INSERT YOUR FAX NUMBER Please respond immediately as to whether or not you have the RENASYS Port, lots listed below. We require your response in order for us to complete our recall in accordance with FDA regulations. Your assistance in this matter is essential to our recall process. Thank you in advance for your quick response to this letter.

Respectfully,

PLEASE INSERT YOUR NAME AND CONTACT DETAILS

_____

Date: _____

Customer Number: _____

We have checked our inventory for the following lot and found the quantity listed below: We understand that Smith & Nephew must have our returns within 30 days of receipt of this notice.

Product #	Lot #	Units Shipped	Units Returned
66800694	50512962		
66800694	50512969		
66800694	50512974		
66800694	50513073		
66800694	50513074		
66800694	50513087		
66800694	50514672		
66800694	50516110		
66800694	50517647		
66800694	50539644		
66800694	50539645		
66800694	50539646		
66800694	50539647		

Product #	Lot #	Units Shipped	Units Returned
66800694	50539648		
66800694	50546339		
66800694	50546340		
66800694	50548244		
66800694	50548245		
66800694	50548246		
66800694	50548247		
66800694	50548248		

We will return this product on: _____
Indicate date you are returning product

We do not have any of the affected products: _____
Indicate with an “X”

Name and Title: _____
Person completing form

Telephone Number: _____