 We are smith&nephew

Wound Management
Smith & Nephew, Inc.
970 Lako Carillon Drive
Suite 110
St. Petersburg, FL 33716

Recall Hotline: 1-888-613-0271
F 727 392-6914
www.smith-nephew.com

July 7, 2011

URGENT: DEVICE RECALL - UPDATE

ATTENTION: Recall Department
AmerisourceBergen
1300 Morris Drive
Chesterbrook, PA 19087

RE: Product Name: UNI-SOLVE® Protective Wipes, SKIN-PREP® Protective Wipes,
REMOVE® Universal Adhesive Remover Wipes
Product Code Number: 402300, 420400, 403100
Lot Number: 9K154, 9K155, 9K149, 9K148

Dear Customer:

On April 6, 2011, Smith & Nephew, Inc., Advanced Wound Management Division sent you a notification regarding a voluntary recall of multiple lot numbers for the various wipes products. Reviewing the data you were provided, it was discovered that the following lots which are part of this voluntary recall were inadvertently omitted. Our shipping records indicate that you received the affected lot of these wipes from 03/16/2010 thru 07/27/2010 as indicated on the attached inventory form.

Product Name	Product #	Lot #
UNI-SOLVE® Protective Wipes	402300	9K154
UNI-SOLVE® Protective Wipes	402300	9K155
SKIN-PREP® Protective Wipes	420400	9K148
REMOVE® Universal Adhesive Remover Wipes	403100	9K149

The purpose of this letter is to provide you with an update to include these lot numbers. These lot numbers are being included in the voluntary recall reported to the FDA.

Accordingly, we are asking you to update your recall records with these new lot numbers information and advise your customers to whom you supply this product.



URGENT PRODUCT RECALL ADDITIONAL LOT NUMBERS

July 18, 2011

To Our Customers,

This letter is to inform you PSS World Medical, Inc. received a letter from Smith & Nephew, Inc. Wound Management notifying about the recall of additional affected lot numbers for the items referenced in the table below. Refer to the enclosed recall notice from Smiths & Nephew for further reasoning of this recall.

GSMS #	Product Code	Lot #
801930	402300	9K154
805434	403100	9K149

HEALTHCARE PROVIDER INSTRUCTIONS:

1. Examine your inventory and quarantine the affected lot numbers referenced in the table above.
 - A. If your facility has Unopened/Full boxes (50 packets per 1 box)
 - o Contact your Gulf South Customer Care team via telephone at 1-800-347-2456 or email customercare@gsms.com to return affected product and obtain credit.
 - B. If your facility has Opened/Partial Boxes or Individual Packets of the affected lot numbers:
 - o Complete the enclosed Destruction Confirmation Form for Partial Boxes or Individual Packets Only
 - o Dispose of affected product per Local, State, and Federal Regulations
 - o Once your Destruction Confirmation Form has been received, credit will be issued.

2. Contact all healthcare facilities your facility has further distributed the above referenced lot numbers.
 - A. Request they return Unopened/Full boxes (50 packets per 1 box) directly to your facility
 - o Contact your Gulf South Customer Care team via telephone at 1-800-347-2456 or email customercare@gsms.com to return affected product and obtain credit.
 - B. Request they dispose of Opened/Partial Boxes or Individual Packets per Local, State, and Federal Regulations
 - o Complete on behalf of the facility, the enclosed Destruction Confirmation Form for Partial Boxes or Individual Packets
 - o Once your Destruction Confirmation Form has been received, credit will be issued.

We sincerely apologize for any inconvenience this notice may have caused you and your staff.

Sincerely,

Quality Assurance Department

1. Destruction Confirmation Form for Opened/Partial Boxes or Individual Packets Only
2. Smith and Nephew Recall Notice

URGENT DEVICE RECALL
Smith & Nephew, Inc.

Action required by you:

Please check your inventory immediately to identify and return the lot numbers shipped to you identified on the attached Form. ~~Product returns to Smith & Nephew must be conducted according to the instructions detailed below.~~

~~Please report the amount of affected lot numbers using the Inventory Form and (1) mail the Form back to us using the postage paid, self-addressed envelope provided, (2) call for any response to 727-392-6914.~~

~~It is very important that you fill in the requested information on the enclosed form for the form to be processed and return the original to us within 10 business days after receipt of this Notice. Even if you do not have the identified products on hand, please complete the form and fax it to us along with sending the original copy to us in the enclosed envelope.~~

Distributors or Kit Packers:

Smith & Nephew is advising all distributors and kit packers who utilize UNI-SOLVE® Protective Wipes, SKIN-PREP® Protective Wipes, and REMOVE® Universal Adhesive Remover Wipes to return unused inventories of affected product lot to the address below. This recall should be carried out to the end user/consumer level.

You are advised to take appropriate action to notify your customers to discontinue use of the affected lots. Your customers should be directed to either destroy or return the product to you. *Note: Smith & Nephew will not accept product returns from customers who do not have an account with us. DO not send this Smith & Nephew letter to your customers to avoid confusion on the return process of the product.*

You should notify your customers/patients to discontinue the use of the affected lot of this product immediately and seek an alternative product.

All Smith & Nephew customers:

~~**Replacement Product:** Upon receipt of your Inventory Form, Smith & Nephew will contact you to review options for inventory adjustments. Please indicate on the attached inventory form the contact information for the person in your organization responsible for purchasing and the inventory management.~~

~~**Product Return:** Please return the affected product by shipping it back to Smith & Nephew via **UPS United Parcel Service** under payment terms plan number **Bill of Lading** and return number **93A95X**. Please mark the box: **UNI-SOLVE® Protective Wipes, SKIN-PREP® Protective Wipes, and REMOVE® Universal Adhesive Remover Wipes**. **CORRECTION AND REMOVE®**. Please return the product to:~~

~~Smith and Nephew
and its logistics~~

~~URGENT DEVICE RECALL~~
~~Smith & Nephew~~

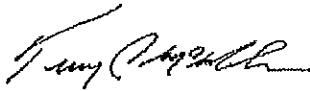
~~Charnice Industrial~~
~~Call 1-800~~
~~Quincy, CA 95094-4400~~

If you have any questions concerning this notification, please contact our Recall Hotline Center at 1-888-613-0271.

RECALL NOTIFICATION
Enclosure/As Stated

We apologize for any inconvenience this may have caused you, your customers or patients.

Sincerely,



Terry C. McMahon
Director, Regulatory Affairs and Quality – North America
Smith & Nephew, Inc.
Advanced Wound Management



Destruction Confirmation Form for Opened/Partial Boxes or Individual Packets ONLY

The intent of this form is to provide confirmation ONLY Opened/Partial Boxes (50 packets per box) and Individual Packets were disposed of according to Local, State, & Federal Regulations. Full Boxes are to be returned and not disposed of.

DO NOT complete this form if you are returning full / unopened boxes

**FAX COMPLETED FORM TO 904-380-4570
(No Cover Sheet required for Fax)**

PRODUCT DESIGNATED FOR DESTRUCTION					
Product Code		Product Code		Product Code	
Lot #		Lot #		Lot #	
Quantity of Packets		Quantity of Packets		Quantity of Packets	
Product Code		Product Code		Product Code	
Lot #		Lot #		Lot #	
Quantity of Packets		Quantity of Packets		Quantity of Packets	
<p>Only Opened/Partial Boxes / Individual Packets have been disposed of in a manner rendering incapable of use. Yes _____ No _____</p> <p>Destroyed By: <i>(Print name)</i></p> <p>Verified By: <i>(Print name)</i></p> <p>Title:</p>					
Branch:	8009				
Prologic Bill To	14872				

**FAX COMPLETED FORM TO 904-380-4570
(No Cover Sheet required for Fax)**

