

**NATIONAL PBM COMMUNICATION · May 20, 2011**

**Recall of Various Adhesive Remover Wipes/Skin Prep Protective Wipes Due to Potential Microbial Contamination**

- Smith & Nephew, Inc., is issuing a voluntary product recall for specific lots of various adhesive remover wipes/skin prep protective wipes used in wound management for the following reasons:
  - The manufacture of these products occurred at the same facility as Triad wipe products, swabs, and swab sticks recalled earlier this year; and
  - Potential for bacterial contamination exists.
- To date, testing on some Smith & Nephew wipe products shows no contamination, but the recall is being implemented as a precaution.

**SEQUESTERING ACTIONS**

- Following the action due dates in Product Recall Office Log # 1148 (available at <http://vawww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>), sequester and then return all remaining product at the CMOP/facility level with affected lot number(s) per manufacturer’s instructions. Please inform your Facility Recall Coordinator when completed.
- The affected lot number(s) are listed below:

DESCRIPTION	LOT #	NDC	UPC	ECONO#
REMOVER ADH WIPE 4031 BX50	OJ190		04056511566	1254036
SKIN PREP NO STING WIPES BX50	0E230, 0E231, 0J290, 0J291, 0J292, 9L169	08026420600	04056511673	2236206
SKIN-PREP PR DRS WIPES 4204 50	0D150, 0G165, 0G184, 0G185, 0G215, 0G282, 0H116, 0H123, 0H266, 0H267, 0J125, 0J126, 0J85, 0K118, 0K119, 0K120, 0K254, 0K255, 0K271, 0K272, 0L164, 0L165, 0L205, 0L206, 0L225, 0L226, 0L242, 0M199, 1A256	08026420400	04056511452	1468701
SMITH&NEPH PROD NUMB 420471	N/A	N/A	N/A	McKesson does not stock
SMITH&NEPH PROD NUMB 59403125	N/A	N/A	N/A	McKesson does not stock
SMITH&NEPH PROD NUMB 59420425	N/A	N/A	N/A	McKesson does not stock
UNI-SOLVE ADH RE WPS 402300 50	0F195, 0F197, 0F224, 0F228, 0F229, 0F239, 0H185, 0H226, 0H228, 0H229, 0K207, 0K208, 0K209, 0K233, 0K234, 0M136, 0M137, 0M149, 0M150, 0M151, 0M238, 1B129	40565115659	04056511565	1469352

- The FDA has not published a complete list of commercially available drug and procedure kits that contain the adhesive remover wipes/skin prep protective wipes. To date, the commercially available procedure kits known to contain the recalled adhesive remover wipes/skin prep protective wipes are:
  - Specialty Centurion kits;
  - Foley Anchor Catheter Securement kit; code FCS200XT; and
  - Smith & Nephew RENASYS G and RENASYS G/P Kits:
    - Renasys G/P – Gauze Dressing Kit with Port Small 66800882,
    - Renasys G/P – Gauze Dressing Kit with Port Medium 66800883,
    - Renasys G/P – Gauze Dressing Kit with Port Large 66800884,
    - Renasys G – Gauze Dressing Kit Small with 10 FR Round Drain 66800491,
    - Renasys G – Gauze Dressing Kit Small with 10mm Flat Drain 66800492,
    - Renasys G – Gauze Dressing Kit Medium with Channel Drain 66800493,
    - Renasys G – Gauze Dressing Kit Medium with 10mm Flat Drain 66800494,
    - Renasys G – Gauze Dressing Kit Large with 19 FR Round Drain 66800495,
    - Renasys G – Gauze Dressing Kit Large with 10mm Flat Drain 66800496,
    - Renasys G – High Output/Fistula Kit with IRR/ASP 28 FR Drain 66800212
 Product Code Number: 59420600

**PATIENT NOTIFICATION ACTIONS**

- Determine whether the affected product was dispensed to any patient(s) for home administration using a 12-month time frame. CMOP data (if available) will be provided by a CMOP representative to Pharmacy Chiefs.
- If an affected lot(s) was dispensed to a patient(s) for home administration, then:
  - Identify the patient(s).

- Contact patient(s) who may have received the affected product for home administration by any appropriate method.
  - A sample letter can be found at:  
<http://vaww.national.cmop.va.gov/PBM/Other%20Documents%20and%20Resources/Recall%20Patient%20Letter%20Template.doc>
  - This template can be altered according to site-specific needs.
- Provide patient(s) with instructions on the following:
  - How to obtain a new supply of product.
  - How to return the product being recalled to the pharmacy.
  - Not to continue using the product with the affected lot number. When the correct product is received, patient should begin using the new product and return the recalled supply as instructed.
- Report any adverse reactions experienced with the use of this product to the VA ADERS program.

**ACTIONS:**

- **Facility Director** (or physician designee): Report completion of actions to the VISN Director.
- **Facility COS and Chief Nurse Executives:** Forward this document to all appropriate providers who handle this agent (e.g., **pharmacy staff, and other medical specialties who may use adhesive remover wipes/skin prep protective wipes**, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate. Report completion of actions to the Facility Director.
- **ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).
- **VISN Directors:** Within 10 business days of issue (due 06/06/2011), communicate to PBM/VAMedSAFE that all patient notification actions have been completed via the Feedback tool: [http://vaww.national.cmop.va.gov/PBM/visn\\_drug\\_recalls\\_alerts/default.aspx](http://vaww.national.cmop.va.gov/PBM/visn_drug_recalls_alerts/default.aspx).