

# Medical Device Alert

Ref: MDA/2011/065 Issued: 07 June 2011 at 14:30

## Device

Alcohol skin preparation pads, swabs and swabsticks manufactured by Triad Group Inc since 2007.

Supplied in various device packs manufactured by:

- Smith & Nephew Wound Management
- Neuro Resource Group Inc.

Problem	Action
<p>The manufacturers issued Field Safety Notices (FSN) for these devices in April 2011, but have not had sufficient confirmation from users that they have received and acted on this information.</p> <p>Copies of the FSNs are in the appendix of this alert, and are also available on the MHRA website.</p> <p>This alert has been issued in support of the manufacturers' actions and it updates MDA/2011/023 (issued 3 March 2011) and MDA/2011/013R (issued 11 February 2011) with details of <b>additional</b> manufacturers' device packs and kits that contain the affected swabs.</p>	<ul style="list-style-type: none"> <li>• Ensure that relevant members of staff are aware of the problem.</li> <li>• Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.</li> </ul>
Action by	
All those who supply and use these affected swabs and device packs.	
CAS deadlines	Contact
<p>Action underway: 21 June 2011</p> <p>Action complete: 05 July 2011</p>	<p><b>Manufacturer/supplier</b></p> <p>See Field Safety Notices in appendix.</p>

## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

#### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All clinical departments
- All outpatient clinics
- All staff
- All wards
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Dentists
- Dermatologists
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Drug treatment service managers
- Haematologists
- Haemodialysis nurses
- Hospital pharmacies
- Hospital pharmacists
- Infection prevention and control directors
- IV nurse specialists
- Medical directors
- Microbiologists
- Needle and syringe programme co-ordinators
- Nursing executive directors
- Paramedics
- Peritoneal dialysis units
- Pharmacists
- Phlebotomists
- Point of care testing co-ordinators
- Purchasing managers
- Risk managers
- Staff supporting patients receiving haemodialysis at home
- Supplies managers

#### Health Protection Agency

Directors for onward distribution to:

- Consultants in communicable disease control
- Health protection nurses

#### Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Chiropodists
- Commissioners of drug treatment services
- Community children's nurses
- Community defibrillation officers
- Community dental practices
- Community diabetes specialist nurses
- Community hospitals
- Community midwives

- Community nurses
- Community pharmacists
- District nurses
- Equipment libraries and stores
- General practitioners
- Health visitors
- Immunisation co-ordinators
- Infection control nurses
- Minor injury units
- Needle and syringe programme co-ordinators
- NHS walk-in centres
- Nutritional nurse specialists
- Occupational health departments
- Palliative care teams
- Pharmaceutical advisors
- Podiatrists
- Practice managers
- Practice nurses
- School nurses
- Walk-in centres

### **Social services**

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Community care staff
- In-house domiciliary care providers (personal care services in the home)
- Occupational health departments

### **Independent distribution**

#### **Establishments registered with the Care Quality Commission (CQC) (England only)**

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## **Contacts**

### **Manufacturer/Supplier**

See appendix.

## **England**

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/065** or **2011/004/012/081/005** or **2011/004/027/081/011**

### **Technical aspects**

Sally Mounter

Medicines & Healthcare products Regulatory Agency

Floor 4

151 Buckingham Palace Road

London SW1W 9SZ

Tel: 020 3080 7168

Fax: 020 8754 3965

Email: [sally.mounter@mhra.gsi.gov.uk](mailto:sally.mounter@mhra.gsi.gov.uk)

**Clinical aspects**

Mr J Plumb  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7128  
Fax: 020 8754 3965  
Email: [jonathan.plumb@mhra.gsi.gov.uk](mailto:jonathan.plumb@mhra.gsi.gov.uk)

**How to report adverse incidents**

Please report via our website <http://www.mhra.gov.uk>  
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

**Northern Ireland**

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.  
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre  
Health Estates Investment Group  
Room 17  
Annex 6  
Castle Buildings  
Stormont Estate  
Dundonald BT4 3SQ  
Tel: 02890 523 704  
Fax: 02890 523 900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)  
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

**How to report adverse incidents in Northern Ireland**

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>  
Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

**Scotland**

Enquiries and adverse incident reports in Scotland should be addressed to:  
Incident Reporting and Investigation Centre  
Health Facilities Scotland  
NHS National Services Scotland  
Gyle Square  
1 South Gyle Crescent  
Edinburgh EH12 9EB  
Tel: 0131 275 7575  
Fax: 0131 314 0722  
Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)  
<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes  
Senior Medical Officer  
Medical Device Alerts  
Welsh Assembly Government  
Cathays Park  
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

MHRA is an executive agency of the Department of Health  
© Crown Copyright 2011

Addressees may take copies for distribution within their own organisations

## Appendix

Wound Management  
Smith & Nephew  
Medical Ltd.  
101 Hessle Road  
Hull HU3 2BN  
England

T 44 (0) 1482 225 181  
F 44 (0) 1482 328 326  
www.smith-nephew.com



April , 2011

**URGENT: Voluntary global recall notification and guidance for REMOVE™ Universal Adhesive Remover Wipes, UNI-SOLVE™ Adhesive Remover Wipes, SKIN-PREP™ Protective Wipes, PERI-PREP Protective Wipes, and NO-STING SKIN-PREP™ Protective Wipes**

**Product Name:** REMOVE Universal Adhesive Remover Wipes, UNI-SOLVE Adhesive Remover Wipes, SKIN-PREP Protective Wipes, PERI-PREP™ Protective Wipes, and NO-STING SKIN-PREP Protective Wipes

**Product Code Number:** See Table 1 below

**Lot Numbers:** See Table 1 below

Dear Customer:

Smith & Nephew Advanced Wound Management (S&N) has made a decision to voluntarily recall, to the end customer level, specific lots of REMOVE Universal Adhesive Remover Wipes, UNI-SOLVE Adhesive Remover Wipes, SKIN-PREP Protective Wipes, PERI-PREP Protective Wipes, and NO-STING SKIN-PREP Protective Wipes, manufactured for Smith & Nephew by The Triad Group. The decision was made to recall these products at the suggestion of the U.S. FDA. It has been determined that these specific lots of products were made in the same facility as other alcohol-containing wipes, swabs and swab sticks manufactured by The Triad Group for itself and other third parties that are the subject of other voluntary recalls due to a potential bacterial contamination issue.

Out of an abundance of caution, Smith & Nephew has decided to voluntarily recall these specific lots of wipe products.

Smith & Nephew is committed to providing our customers with high quality, reliable products. We are, therefore, taking this action to remove the specific lots of the listed products from the market as a prudent, cautionary and conservative measure to assure patient safety and product performance.

Smith & Nephew regrets the inconvenience this has caused its customers. As a result, Smith & Nephew has terminated its agreement with The Triad Group and secured replacement products from an alternative source. The new and approved supplier is already manufacturing product to minimise supply disruption to Smith & Nephew customers.

**Action required by you:**

Smith & Nephew is advising all distributors, kit packers and suppliers to immediately discontinue use of the specific products and issue a sub-recall to their customers by following their individual sub-recall procedures.

Smith & Nephew is advising end users, caregivers, and patients to discontinue use of these specific lots immediately and responsibly dispose of products with the lot numbers listed below. Prior to disposal, end-users, patients, and caregivers should contact their supplier/distributor for instructions about their specific return policies, recall procedures, and how to order replacement products.

We apologize for any inconvenience this may have caused you.

Yours Sincerely,

Liam Phelan  
Senior Vice President, Healthcare Systems  
Smith & Nephew  
Advanced Wound Management

Table 1: Product and lot numbers for recall

Page 1 of 2

S&N Product Code Number	Product Name	Lot numbers
5132	PERI PREP Wipes Box of 50	OC232, OG243
420400	SKIN PREP Wipes Box of 50	OD169, OD182, OD190, OD150, OD200, OF164, OF165, OF182, OF183, OF184, OG137, OG165, OG184, OG185, OG215, OG282, OH116, OH117, OH123, OH266, OH267, OJ124, OJ125, OJ126, OJ85, OK118, OK119, OK120, OK254, OK255, OK271, OK272, OL164, OL165, OL205, OL206, OL225, OL226, OL227, OL241, OL242, OM199, OM200, O6K120, 1A246, 1A247, 1A248, 1A256, 1A257, 1A258
420471	SKIN PREP Wipes Box of 1000	OD149, OF184, OJ127, OM109, 1A277
59420425	SKIN PREP Wipes, Box of 50	OG117, OG225, OJ146, OJ147, OK78, OM198
403100	REMOVE Wipes Box of 50	OE145, OE146, OE194, OE210, OE211, OG138, OH135, OH248, OJ190, OJ232, OL147, OM176, OM177, 1A117, 1B112, 1B128
403120	REMOVE Wipes Box of 50	OL163, 1A193
59403125	REMOVE Wipes bOX OF 50	OE219, OE226, OF242, OG116, OH256, OJ233, OJ262, OJ263, OM178, OM179, 1A106, 1A181, 1A182, 1A192
402300	UNISOLVE Wipes Box of 50	OF195, OF197, OF198, OF223, OF224, OF228, OF229, OF239, OH185, OH226, OH228, OH229, OK207, OK208, OK209, OK233, OK234, OM136, OM137, OM149, OM150, OM151, OM238, 1A103, 1B129, 1B130, 1B131, 1B132
59420600	NO STING SKIN PREP Wipes Box of 50	9K150, 9K151, 9L169, 9L170, OE230, OE231, OJ290, OJ291, OJ292



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

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

April 13, 2011

**URGENT: DEVICE CORRECTION**

ATTENTION

Company Name  
Address  
City,  
Country

RE: **Product Name: NO-STING SKIN-PREP™ Protective Wipes (supplied as a component of the following 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
- NO STING SKIN PREP **Product Code Number:** 59420600

Dear Customer:

In order for Smith & Nephew to conduct and document the corrective action of the multiple lot numbers of NO-STING SKIN-PREP™ Protective Wipes (product code 59420600) which are supplied as a component part of several RENASYS G and RENASYS G/P Dressing Kits as referenced above, we require completion of the Inventory Form, listing the amount of the **NO-STING SKIN-PREP™ Protective Wipes** of the affected lot numbers in the Units Disposition column. To do so, identify whether you have removed the unopened packets from the RENASYS G or RENASYS G/P dressing kit and safely dispose of the prep pad and sachet in a responsible manner

If you do not have inventory, please write “0” in that column **and**:

**Please edit the list to include your preferred methods of contact**

- (1) mail the Form back to us using the postage-paid, self-addressed envelope provided;**
- (2) also fax your response to: INSERT YOUR FAX NUMBER**

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.

Respectfully,

John Painter, Recall Coordinator



NEURO RESOURCE GROUP

**Letter to NRG Individual Customers**

Dear Neuro Resource Group Customer,

This is to inform you of a voluntary product recall of alcohol wipes which are packaged with NRG devices.

Neuro Resource Group, Inc. (NRG) has become aware of the market recall of Triad Group's alcohol prep pads, alcohol swabs, and alcohol swabsticks manufactured by Triad in the United States and marketed under various brand names, (<http://www.fda.gov/Safety/Recalls/ucm239219.htm>). The Triad Group alcohol prep pads are co-packaged and distributed with NRG devices to customers in the United States and internationally.

- According to the Food and Drug Administration's (FDA) Medwatch communication, the recall was initiated due to concerns about potential contamination of the Triad Group's products with the bacteria, *Bacillus cereus*. This recall involves those products marked as sterile as well as non-sterile. Use of contaminated alcohol prep pads, alcohol swabs, and alcohol swabsticks could lead to life-threatening infections, especially in at-risk populations, including immune suppressed and surgical patients. **The Triad wipes may also be labeled “Select”; “Select Medical Products”; “PSS Select”, or “PSS World Medical, Inc.” The subject Triad/Select alcohol wipes previously provided with NRG devices should be discarded immediately.** NRG is currently providing alcohol wipes that are not subject to recall.

It is important to note, that **NRG devices are not contaminated and may continue to be used in accordance with the instructions for use. The alcohol wipes were provided strictly as a cleaning convenience.** Patients and healthcare providers should **not** use the Triad/Select alcohol prep pads packaged with these devices and should instead use an alternate alcohol prep pad that is not involved with the Triad Group recall, or alternatively use a gauze or tissue pad in conjunction with 70% isopropyl alcohol for cleaning. For replacement wipes, customers may contact NRG customer service at 1-877-314-6500.

Further information about the Triad Group recall can be found on the FDA website at: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239319.htm><sup>10</sup>.

Patients should consult their healthcare provider for further information. Healthcare providers with questions may contact NRG Customer Service at 1-877-314-6500 between the hours of 8 am and 5 pm Central Time, USA.

**US Contact**

Sarah Magee  
Phone: +1-972-665-1810 ext 231

**EU Contact**

Emergo Group  
Evangeline Loh / Kelly Jacobs  
Molenstraat 15, 2513 BH, The Hague, The Netherlands  
Phone: +31 70 345 8570

1100 JUPITER ROAD | SUITE 190 | PLANO | TX | 75074 | PH 972-665-1810 | FAX 972-665-1814