

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/68

Issued: 22 September 2005

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Johnson & Johnson Wound Management Sterile Ray-Tec™ X-Ray Detectable Swabs - recall.	▶ ①
Problem: Johnson & Johnson Wound Management is conducting a voluntary recall of all Sterile Ray-Tec™ X-ray detectable swabs. A packaging defect means that the sterility of the swabs and the packaging may have been compromised.	▶ ②
Action by: All those involved in the use, supply and/or distribution of these devices.	▶ ③
<ul style="list-style-type: none"> • Identify, quarantine and do not use all swabs subject to this recall. • Ensure that all relevant staff are aware of this recall. • Contact the manufacturer to arrange return of affected stock. (see appendix) 	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5	▶ ⑤
Contacts Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Johnson & Johnson Wound Management Sterile Ray-Tec™ X-Ray detectable swabs.

The affected product codes are:

MRT024, MRT026, MRT027, MRT031, MRT034, MRT042,
MRT044, MRT052, MRT054, MRT061, MRT062, MRT072,
P53563, P53584, P53589.

Ray-Tec swabs that are supplied as non-sterile, for sterilization locally, are not affected by this recall.

2. PROBLEM:

Johnson & Johnson Wound Management has informed MHRA that the sterility of these devices may be compromised due to small holes in the outer packaging. Whilst there is still another layer of packaging protecting the swabs, the sterility of the swabs or that of the sterile field cannot be guaranteed.

3. ACTION BY:

All those involved in the use, supply and/or distribution of these devices.

4. ACTION:

- Follow the advice in the manufacturer's recall letter (see appendix) and contact the manufacturer to arrange return of affected stock.
- Obtain alternative stocks of sterile x-ray detectable swabs.
- We understand that this product is not supplied into Northern Ireland under a regional supplies contract, but this Alert is distributed as the products may have been sourced locally.
- RSS can give advice on alternative suppliers, contact: Sam Blackley, Tel: 028 90667799.
- If emergency surgery is required and there are no alternative swabs available, the absence of air in the vacuum pack may indicate the integrity of the outer packaging has not been compromised.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Maternity Wards
- Pharmacy Managers
- Directors of Public Health
- Community Care Staff
- Day Care Centres
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSSRIA
- Sterile Services Departments
- Operating Theatre Staff
- Infection Control Staff
- Accident & Emergency Departments
- Coronary Care
- Intensive Care
- Surgeons
- Day Procedure Units

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:
Johnson & Johnson Wound Management
Gargrave
North Yorkshire
BD23 3RX

Tel: 0800 783 7157
Fax: 01344 864 018

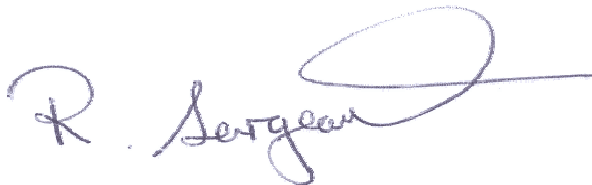
E-mail: contact@medgb.jnj.com

Enquires to NIAIC should quote reference number MDEA(NI)2005/68 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2005/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety



Attention: Theatre Manager and Supplies Manager

<p>PRODUCT</p>	<p>RAY-TEC* X Ray Detectable Gauze Swabs - Sterile product codes MRT024, MRT026, MRT027, MRT031, MRT034, MRT042, MRT044, MRT052, MRT054, MRT061, MRT062, MRT072, P53563, P53584, P53589</p>
<p><i>REASON</i></p>	<p>Johnson & Johnson Wound Management, a division of Johnson & Johnson Medical is conducting a voluntary product recall of all RAY-TEC* X Ray Detectable Gauze Swabs - Sterile. The codes of affected product are above.</p> <p>We have initiated a voluntary recall for the codes affected due to an audit which has uncovered a small percentage of product exhibiting minute perforations in the outer packaging, which means the integrity of the packs cannot be guaranteed. Please note that this voluntary recall is limited to the specific codes only. No other codes supplied by Johnson & Johnson Wound Management are affected.</p> <p>The voluntary recall is being conducted with the full knowledge of the MHRA.</p> <p>DO NOT USE ANY RAY-TEC* STERILE CODES</p> <p>We need your help in ensuring that <u>all affected codes numbers</u> are located and accounted for, and returned to Johnson & Johnson Wound Management, Gargrave, N. Yorkshire.</p> <p>This voluntary recall affects no other Johnson & Johnson Wound Management products.</p>
<p><i>ACTION</i></p>	<ol style="list-style-type: none"> 1. Examine your inventory immediately to determine if you have affected product on hand. Remove the affected product codes. 2. Fill out the reply note and fax to Johnson & Johnson Wound Management on 01344 864018, even if you do not have affected product. If you have product to be returned, fill out and enclose the packing slip with the product and Johnson & Johnson Wound Management will contact you to arrange to collect the product. <p>1 Johnson & Johnson Wound Management Fax Contact Number 01344 864018</p> <p>Customer Service or your local Key Account Manager will assist you in the completion of this voluntary recall.</p>
<p>OTHER INFORMATION</p>	<p>Johnson & Johnson Wound Management UK will process your return upon receipt of the affected product and credit the value in full. Please indicate the value of the product to be returned and the supply route.</p> <p>Since this is a disposable single use device, Johnson & Johnson Wound Management will not accept returns of used product for health and safety reasons, it is your responsibility to take this into consideration.</p> <p>Please share this information with all of the appropriate staff at your location. We apologize for any inconvenience this will cause you, but rest assured it is our utmost intent to make this process as easy for you as possible.</p> <p>If you have additional questions about this action, please feel free to contact your Key Account Manager or Customer Service Centre, Bracknell 0800 783 7157 or via email at contact@medgb.jnj.com</p>



URGENT: DEVICE RECALL

Recalled Product Codes

MRT024, MRT026, MRT027, MRT031, MRT034, MRT042, MRT044 MRT052, MRT054, MRT061,
MRT062, MRT072, P53563, P53584, P53589

RECALL ALL Product

Code	Number of CASES of product to be uplifted	Value	Location
MRT024			
MRT026			
MRT027			
MRT031			
MRT034			
MRT042			
MRT044			
MRT044			
MRT061			
MRT062			
MRT072			
P53563			
P53584			
P53589			
Contact Name	Telephone	NHS Trust/Customer Address	