


# Medical Device Alert

Ref: MDA/2013/038 Issued: 12 June 2013 at 14:00

Device	
<p>Rusch Belly Bag urine collection bag with hip belt. Specific product codes.</p> <p>Manufactured by Teleflex Medical.</p>	

Problem	Action
<p>Packaging may be compromised and therefore the sterility of the product cannot be guaranteed.</p> <p>If non-sterile products are used, there is a risk of infection.</p>	<p>Identify and quarantine affected products.</p> <p>Contact patients who have received affected stock and retrieve any unused devices.</p> <p>Teleflex Medical <a href="#">issued a Field Safety Notice (FSN) on 27 March 2013</a> recalling all batches of the affected product codes.</p>
Action by	<p>Return the acknowledgement form to Teleflex and arrange for the return and replacement of unused affected devices.</p>
<p>All healthcare workers who use these devices, or are responsible for patients who use these devices in their own home.</p> <p>Personnel involved in the purchase, supply and distribution of these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 27 June 2013</p> <p>Action complete: 12 July 2013</p> <p><b>Note: These deadlines are for unused affected bags to be removed from use.</b></p>	<p><b>Manufacturer</b></p> <p>Teleflex Medical</p> <p>Hélène Sauvage</p> <p>Tel: 01494 532 761</p> <p>Email: <a href="mailto:orders.uk@teleflex.com">orders.uk@teleflex.com</a></p>

## Device

All lot numbers of the following product codes are affected:

- Belly Bag, product code B1000 (NHS Supply Chain code GDW502)
- Belly Bag with 24 inch drain, product code B1000CT
- Belly Bag with sample port, product code B1000P

## Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS England area teams (chief executives)
- NHS England regional teams
- NHS trusts in England (chief executives)
- OFSTED (directors of children's services) for information
- 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:

- Chief pharmacists
- Clinical governance leads
- Community children's nurses
- Community hospitals
- Community nurses
- Continence nurse specialists
- District nurses
- Equipment stores
- Health visitors
- Neurology units
- Nursing executive directors
- Outpatient clinics
- Purchasing managers
- Risk managers
- Spinal injury units
- Supplies managers
- Urology departments

### NHS England local area teams

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

- Community pharmacists
- General Practitioners
- Practice managers
- Practice nurses

### Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes

## 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)
- Care homes providing personal care (adults)
- Domiciliary care providers
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

### Establishments registered with OFSTED

This alert should be read by:

- Children's services
- Educational establishments with beds for children
- Residential special schools

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

Hélène Sauvage

IDA Business & Technology Park, Garrycastle, Dublin Road, Athlone, Co. Westmeath, Ireland

Tel: 01494 532 761

Fax: 01494 524 650

Email: [orders.uk@teleflex.com](mailto:orders.uk@teleflex.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/038** or **2013/003/027/291/039**

### Technical aspects

Ainsley Wickens or Ian Sealey

Medicines & Healthcare Products Regulatory Agency

Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7273 / 6691 Fax: 020 8754 3965

Email: [ainsley.wickens@mhra.gsi.gov.uk](mailto:ainsley.wickens@mhra.gsi.gov.uk)  
[ian.sealey@mhra.gsi.gov.uk](mailto:ian.sealey@mhra.gsi.gov.uk)

### Clinical aspects

Mark Grumbridge

Medicines & Healthcare Products Regulatory Agency

Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

Tel: 020 3080 7128 Fax: 020 8754 3965

Email: [mark.grumbridge@mhra.gsi.gov.uk](mailto:mark.grumbridge@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:

Improving Patient Safety Team

Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ

Tel: 029 2082 3922 Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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