

Medical Device Alert

Ref: MDA/2011/045 Issued: 13 May 2011 at 12:30

Device

Molnlycke Health Care Procedure Pak[®]s (for lipolysis and sperm retrieval) containing BD Microlance 30G x 1/2" hypodermic needle.

Product codes 97016297-01 & 97031992-00.

Specific lot numbers.

Problem	Action
<p>The manufacturer issued a Field Safety Notice (FSN) for these devices in March 2011, but has not had sufficient confirmation from users that they have received and acted on this information.</p> <p>A copy of the FSN is in the appendix of this alert, and it is also available on the MHRA website.</p> <p>This alert has been issued in support of the manufacturer's actions.</p>	<ul style="list-style-type: none"> • Ensure that relevant members of staff are aware of the problem. • Carry out the actions described in the manufacturer's FSN, including sending any confirmation requests.
<h3>Action by</h3>	
<p>All healthcare workers who use these devices.</p> <p>Personnel involved in the purchase, supply and distribution of these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 27 May 2011</p> <p>Action complete: 10 June 2011</p>	<p>Manufacturer/supplier Caroline Price Molnlycke Health Care Tel: 0161 777 2679 Fax: 0161 621 2045 Email: vigilance@molnlycke.com</p>

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)

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 theatres
- Clinical governance leads
- Fertility clinics
- Medical directors
- Nursing executive directors
- Outpatient departments
- Plastic surgeons
- Supplies departments

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Fertility clinics
- Hospitals in the independent sector
- Plastic surgeons
- 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 and requesting this facility.

Contacts

Manufacturer/Supplier

Caroline Price
Molnlycke Healthcare
Two Omega Drive
Irlam
Greater Manchester
M44 5BJ

Tel: 0161 777 2679

Fax: 0161 621 2045

Email: vigilance@molnlycke.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/0045** or **2011/003/003/081/014**

Technical aspects

Ainsley Wickens or Sharon Knight
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7273 / 7202

Fax: 020 8754 3965

Email: ainsley.wickens@mhra.gsi.gov.uk
sharon.knight@mhra.gsi.gov.uk

Clinical aspects

Jonathan 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

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

<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

<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

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Addressees may take copies for distribution within their own organisations

Appendix



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FIELD SAFETY NOTICE

Commercial name of the affected product: Mölnlycke Health Care Procedure Pak®

Type of action: Return of the device

Attention: Theatre Manager (UK)

Details on affected devices:

Product code	Batch Number
97031992-00	10162430
97016297-01	10500874
97016297-01	10285599
97016297-01	10257704
97031992-00	10355413

Description of the problem:

Mölnlycke Health Care have been advised by Becton Dickinson (BD) of a potential manufacturing irregularity concerning certain batches of the Microlance™ 30G x ½" Needle which is added to Mölnlycke Health Care Procedure Pak®. A small number of needles within the trays listed may be occluded or partially occluded.

Advise on action to be taken by the user:

- Please identify and quarantine all affected unused product at your facility.
- Mölnlycke Health Care will collect or arrange for collection all affected unused product from your facility.
- Patient follow-up related to use of the affected device should be undertaken. If any adverse event is suspected, Mölnlycke Healthcare should be informed.
- Any adverse events relating to the use of the affected ProcedurePak® products should be reported immediately to Mölnlycke Health Care.
- Please complete the attached confirmation form and send to the attention of:
Caroline Price, Vigilance Associate
Tel: +44 (0)161 777 2679
Fax: +44 (0)161 621 2045
E-mail: vigilance@molnlycke.com



Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Caroline Price
Vigilance Associate
Mölnlycke Health Care
2 Omega Drive
Irlam
M44 5BJ
United Kingdom

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency in Sweden and our Notified Body BSi.

Yours sincerely,

Caroline Price
Vigilance Associate

PLEASE COMPLETE AND RETURN THIS FORM TO:

Caroline Price, Vigilance Associate
Mölnlycke Health Care
2 Omega Drive
Irlam
Manchester
M44 5BJ

Tel: +44 (0)161 777 2646
Fax: +44 (0)161 621 2045
E-mail: vigilance@molnlycke.com

Ref - 50032902

