

# Medical Device Alert

Ref: MDA/2011/069 Issued: 20 June 2011 at 11:00

## Device

Pelisppec vaginal specula including those with smoke extractor, those in light source packs and IUD procedure packs.

Manufactured by Pelican Feminine Healthcare.

All product codes.

Lot numbers: week 18/2006 to week 17/2011 inclusive.

Problem	Action
<p>The peel pouch of approximately 1% of these products may be damaged and the sterility compromised.</p> <p>The manufacturer has recalled all products in these specified lot numbers.</p>	<p>If you are affected by this recall:</p> <ul style="list-style-type: none"> <li>ensure that relevant members of staff are aware of this problem.</li> <li>carry out the actions described in the manufacturer's <a href="#">Field Safety Notice</a> (issued 31 May 2011).</li> </ul>
Action by	
<p>All healthcare workers who use these devices. Personnel involved in the purchase, supply and distribution of these devices.</p>	<p>Where no alternative devices are available, you are advised to use existing stock having first inspected the packaging for damage around the handle area before use (see example of damage in Figure 1).</p> <p>Do <b>not</b> use these products for the insertion or removal of IUDs, or in other circumstances where the patient or the procedure requires a sterile device.</p>
CAS deadlines	Contact
<p>Action underway: 27 June 2011</p> <p>Action complete: 04 July 2011</p>	<p><b>Manufacturer</b>            Paul Eakin            Pelican Feminine Healthcare            Tel: 029 2074 7400            Fax: 029 2074 7757            Email: <a href="mailto:recall@pelicanfh.co.uk">recall@pelicanfh.co.uk</a></p>

## Device

Product codes of affected devices:

400091, 400100, 400101, 400102, 400103, 400104, 400105, 400106, 400107, 400108, 400111, 400112, 400113, 400200, 400206, 400207, 400208, 400209, 400351, 400352, 400361 and 400362.

## Action

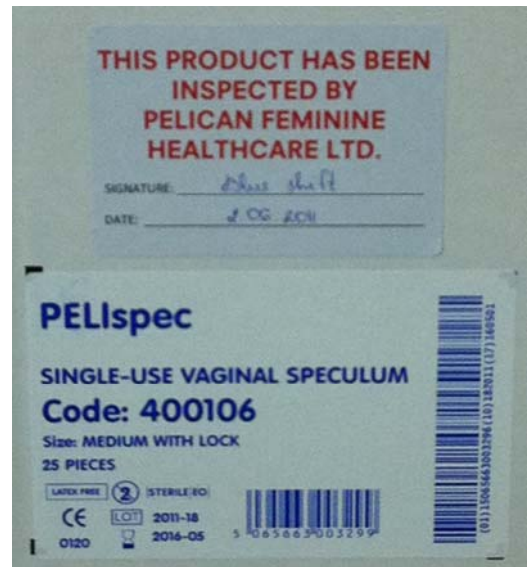
As an interim measure, to reduce supply problems, the manufacturer will inspect returned stock and resupply undamaged devices for use. Products which have been inspected can be identified by the presence of an inspection label (see Figure 2).

If no alternative devices are available, where the benefits of continuing to use the recalled speculum outweigh the risks, users should retain sufficient stock to maintain services until alternative devices can be supplied provided actions described above are completed.

**Figure 1 Example of damaged packaging**



**Figure 2 Example of inspection label**



## 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)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (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:

- A&E departments
- All wards
- Clinical governance leads
- Colposcopy departments
- Day surgery units
- Equipment stores
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Infection prevention and control directors
- Maternity units
- Midwifery departments
- Midwifery staff
- Nursing executive directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric wards
- Purchasing managers
- Risk managers
- Sexual health clinics
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urology departments

### **Primary care trusts**

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

- Community hospitals
- Community midwives
- Family planning clinics
- General practitioners
- NHS walk-in centres
- Practice managers
- Practice nurses

## **Independent distribution**

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

This alert should be read by:

- Clinics
- 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

Paul Eakin  
Pelican Feminine Healthcare  
Cardiff Business Park  
Llanishen  
Cardiff  
CF14 5WF  
Tel: 029 2074 7400  
Fax: 029 2074 7757  
Email: [recall@pelicanfh.co.uk](mailto:recall@pelicanfh.co.uk)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/069** or **2011/006/002/291/003**

### Technical aspects

Ms Ainsley Wickens or Mrs Sara Vincent  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7273 / 7169  
Fax: 020 8754 3965  
Email: [ainsley.wickens@mhra.gsi.gov.uk](mailto:ainsley.wickens@mhra.gsi.gov.uk)  
[sara.vincent@mhra.gsi.gov.uk](mailto:sara.vincent@mhra.gsi.gov.uk)

### Clinical aspects

Dr Susanne Ludgate  
Medicines & Healthcare products Regulatory Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 6800  
Fax: 020 8754 3965  
Email: [susanne.ludgate@mhra.gsi.gov.uk](mailto:susanne.ludgate@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)