

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/72

Issued: 23 August 2007

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**HEALTH ESTATES**

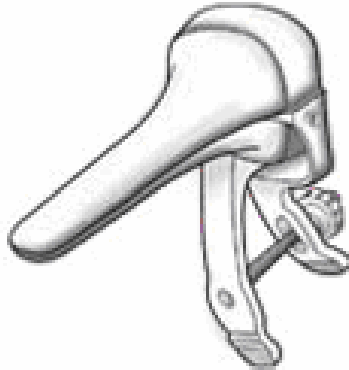
creating healing environments

	Section
<p><b>Medical Device/Equipment:</b> Vaginal specula: all single-use Cusco screw type vaginal specula manufactured by North Eos.</p>	▶ ①
<p><b>Problem:</b> All single-use Cusco screw type specula supplied before 27 February 2007 have been wrongly labelled as sterile instead of clinically clean. Other models of vaginal specula from this manufacturer are not affected.</p>	▶ ②
<p><b>Action by:</b> Users of these devices.</p>	▶ ③
<p><b>Action:</b> Any product labelled as sterile should be withdrawn from use to avoid confusion over its sterility status.</p>	▶ ④
<p><b>Distributed by NIAIC to:</b>                      Chief Executive of each HSS Board                      Chief Executive of each HSS Trust                      Chief Executive of each Agency                      NIAIC Liaison Officers                      General Medical Practitioners</p>	▶ ⑤
<p><b>Contacts</b> Details of supplier contacts and NIAIC contact for technical aspects.</p>	▶ ⑥
<p><b>Feedback Requirements to NIAIC</b> None Required</p>	▶ ⑦

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

## 1. DEVICE/EQUIPMENT:

North Eos disposable vaginal speculum (Cusco screw type)  
Product code: Eos Spec Type 1



## 2. PROBLEM:

Testing has shown that these specula have been supplied in a clinically clean, non-sterile state. The manufacturer altered their packaging on 27 February 2007 to indicate this. Products already distributed as sterile are to be withdrawn from use.

## 3. ACTION BY:

Users of these devices.

## 4. ACTION:

Any product labelled as sterile should be withdrawn from use to avoid confusion over its sterility status.

## 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
- Nurse Directors
- Medical, Nursing and Care Staff
- Supplies Staff (RSS)
- Gynaecologists
- Gynaecology Wards
- Maternity Units
- Medical and Radiation Oncologists
- Midwifery Staff
- Obstetricians
- Obstetrics Nurses
- Outpatient Theatre Managers
- Outpatient Theatre Nurses
- Sexual Health Clinics
- Urology Surgeons
- Family Planning Units
- Practice Nurses
- Directors of Public Health
- Independent Health and Social Care Providers – Private Clinics through RQIA
- Outpatient Departments
- Infection Control Staff
- Accident & Emergency Departments
- Day Procedure Units

## 6. CONTACTS:

Enquiries to supplier should be addressed to:

Martin Waeschle  
Albert Waeschle  
Unit11  
Balena Close  
Creekmoor Industrial Estate  
Poole  
Dorset BH17 7DX  
Tel: 01202 601 177  
Fax: 01202 650 022  
E-mail: Waeschlem@aol.com

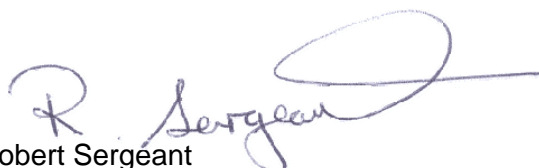
Enquiries to NIAIC should quote reference number MDEA(NI)2007/72 and be addressed to:

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](mailto: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)2006/01. 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](http://www.dhsspsni.gov.uk/niaic)

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