

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/039

Issued: 10 May 2007

For:

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



**HEALTH ESTATES**

creating healing environments

	Section				
<p><b>Medical Device/Equipment:</b> Flexible endoscopes manufactured by Olympus, distributed in the UK by KeyMed Limited.</p>	▶ ①				
<p><b>Problem:</b> The outer sheath and light guide tube of Olympus flexible endoscopes may be damaged by direct exposure to ultraviolet (UV) light, as used in some endoscope storage and drying cabinets.</p>	▶ ②				
<p><b>Action by:</b> Lead staff involved in:</p> <ul style="list-style-type: none"> <li>the reprocessing and use of flexible endoscopes</li> <li>the procurement of flexible endoscopes and associated storage and drying cabinets</li> <li>trust risk management, health and safety and decontamination staff.</li> </ul>	▶ ③				
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>Avoid placing Olympus flexible endoscopes in storage and drying cabinets where UV light shines directly onto the endoscope.</li> <li>If no other suitable storage or drying cabinet is available carry out a risk assessment for the continued use of these cabinets for storing and drying Olympus flexible endoscopes.</li> <li>Before purchasing a new endoscope ensure that it is compatible with local endoscope storage and drying cabinets.</li> </ul>	▶ ④				
<p><b>Distributed by NIAIC to:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">Chief Executive of each Agency</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>NIAIC Liaison Officers</td> </tr> </table>	Chief Executive of each HSS Board	Chief Executive of each Agency	Chief Executive of each HSS Trust	NIAIC Liaison Officers	▶ ⑤
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<p><b>Contacts</b> Details of supplier contacts and NIAIC contacts 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:

Flexible endoscopes manufactured by Olympus, distributed in the UK by KeyMed Limited.

## 2. PROBLEM:

KeyMed has informed the MHRA of the increase in Olympus flexible endoscopes being returned to them for repair due to damage to the outer sheath of the insertion tube and light guide tube. Olympus believes that this damage is caused by prolonged exposure to UV light, as used in some endoscope storage and drying cabinets and causes significant deterioration in the outer coating of all Olympus flexible endoscopes.

This type of damage to the outer sheath of the flexible endoscope insertion tube and light guide tube may:

- cause trauma to the patient
- affect the functionality of the endoscope
- allow ingress of fluids into the endoscope
- inhibit effective decontamination of the endoscope by allowing micro-organisms to be retained in the damaged area of the endoscope
- reduce the number of endoscopes available for use in the unit whilst the affected endoscope is being repaired.

## 3. ACTION BY:

Lead staff involved in:

- the reprocessing and use of flexible endoscopes
- the procurement of flexible endoscopes and associated storage and drying cabinets
- trust risk management, health and safety and decontamination staff.

## 4. ACTION:

- Avoid placing Olympus flexible endoscopes in storage and drying cabinets where UV light shines directly onto the endoscope.
- If no other suitable storage or drying cabinet is available carry out a risk assessment for the continued use of these cabinets for storing and drying Olympus flexible endoscopes.
- Before purchasing a new endoscope ensure that it is compatible with local endoscope storage and drying cabinets.

## 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
- Estates Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Supplies Staff (RSS)
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- Sterile Services Departments
- Operating Theatre Staff
- Infection Control Staff
- Accident & Emergency Departments
- Intensive Care
- Day Procedure Units

## 6. CONTACTS:

Enquires to supplier should be addressed to:

Roger Gray  
General Manager - QA/RA  
KeyMed Ltd  
KeyMed House  
Stock Road  
Southend-on-Sea  
SS2 5QH

Tel: 01702 444 276 (direct line)

Fax: 01702 445 112

E-mail: [Roger.Gray@keymed.co.uk](mailto:Roger.Gray@keymed.co.uk)

Enquires to NIAIC should quote reference number MDEA(NI)2007/ 039 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

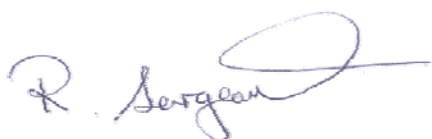
Tel: 028 9052 3868

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*