

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/76

Issued: 18 December 2006

For:

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



**HEALTH ESTATES**

creating healing environments

	Section
<p><b>Medical Device/Equipment:</b> Wash set bowls used in Sorin Group Dideco <i>Electa</i> and <i>Compact</i> autotransfusion machines.</p>	▶ ①
<p><b>Problem:</b> Due to manufacturing problems producing misshapen bowls, there have been reports of difficulties with the insertion of the wash set bowl, which can result in black particles being deposited inside the wash bowl during use. This could lead to the infusion of particles.</p>	▶ ②
<p><b>Action by:</b> Perfusionists, ODPs, theatre nurses, anaesthetists and theatre managers.</p>	▶ ③
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>• Stop using affected lots of bowls, unless no alternative is available.</li> <li>• If using a bowl from the affected lot, ensure that it can be inserted as described in the instructions overleaf. Sorin also recommends using a blood filter under these circumstances.</li> <li>• If any defective bowls are detected, ensure that the manufacturer is contacted to arrange collection and replacement of affected stock.</li> </ul>	▶ 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</p>	▶ ⑤
<p><b>Contacts</b> Details of manufacturer/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:

The Dideco wash set bowls are disposable bowls used with the Electa and Compact autotransfusion machines. These devices are distributed worldwide.

The affected product codes which are available in the UK are:

code	Product	KIT	code	Product	KIT
4125	740C/125	Compact Wash Set	4162M	740E/55	Electa Wash Set
4126	740C/175	Compact Wash Set	4163M	740E/125	Electa Wash Set
4127	740C/225	Compact Wash Set	4164M	740E/175	Electa Wash Set
4149	740C/55	Compact Wash Set	4165M	740E/225	Electa Wash Set
4145	740C/125	Compact ATS Kit	4167M	745E/55	Electa ATS Kit
4146	740C/175	Compact ATS Kit	4168M	745E/125	Electa ATS Kit
4147	740C/225	Compact ATS Kit	4169M	745E/175	Electa ATS Kit
4148	740C/55	Compact ATS Kit	4170M	745E/225	Electa ATS Kit

**This recall is for all lots produced between the end of January and July 2006.** The affected lots can be identified by the lot number starting from 0601230037, and include the following:

060124XXXX, 060125XXXX, 060126XXXX, 060127XXXX, 060128XXXX, 060129XXXX, 060130XXXX, 060131XXXX

Where X can be any number

Also for all lot numbers which contain first four digits as:

0602XXXXXX  
0603XXXXXX  
0604XXXXXX  
0605XXXXXX  
0606XXXXXX  
0607XXXXXX

## 2. PROBLEM:

The manufacturer has identified a manufacturing error which has resulted in misshapen wash bowls being produced during the first half of this year.

There have been reports of these defective wash set bowls being inserted with difficulty into the corresponding auto-transfusion machines. This has resulted in the rotating bowl seal deteriorating whilst centrifuging, producing black particles as a result of this wear inside the bowl, as well as generating excessive noise. Therefore there is the potential risk for these particles to be **infused into the patient**.

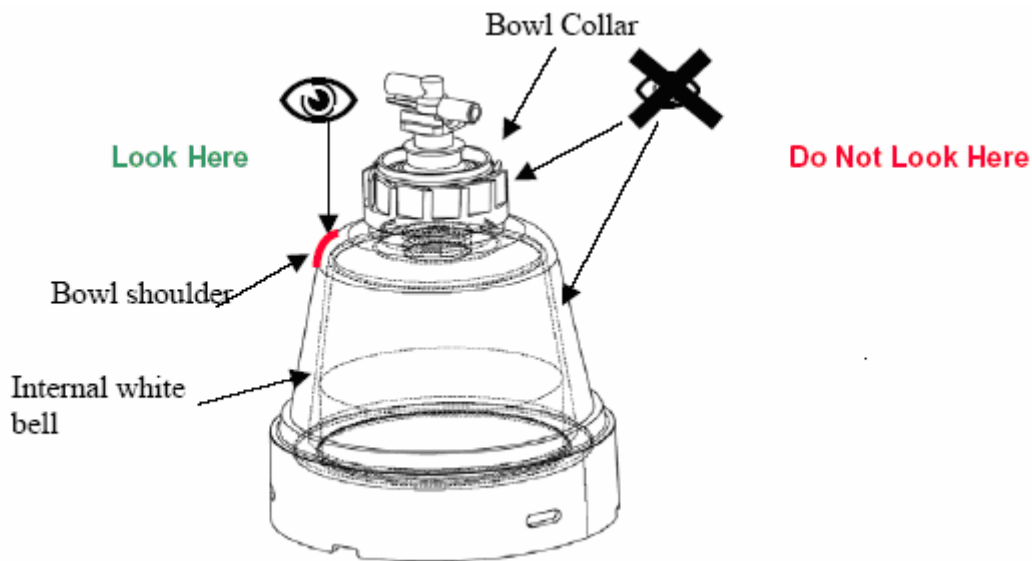
## 3. ACTION BY:

Perfusionists, ODPs, theatre nurses, anaesthetists and theatre managers.

## 4. ACTION:

- Stop using of affected lots of bowls, unless no alternative is available.
  - Insert the bowl correctly as described in the relevant 'instructions for use'. A summary is given below.
- 1) Viewing the bowl from directly above, insert the bowl using two hands.
  - 2) Press firmly until a distinct 'snap' or 'click' is heard as the bowl connects with the centrifuge plate. If no sound is heard, then remove the bowl, rotate 120° and attempt reinsertion. If a 'snap' or 'click' is still not obtained, replace the wash set and quarantine the defective one.

- 3) If the bowl has been secured, rotate it manually to ensure that it rotates on its axis: ensure proper alignment by viewing from directly above the 'shoulder' of the bowl (see figure below). If the bowl is not rotating correctly, replace the wash set and quarantine the defective one.



- 4) Rotate using machine centrifuge by pressing STAND BY and the PRIME key in sequence. Observe the bowl rotation for around 20 seconds and then press STOP. If abnormal noise or vibration occurs, do not use the bowl. Replace the wash set and quarantine the defective one.
- If defective bowls are detected, ensure that the manufacturer is contacted to arrange collection and replacement of affected stock.

It is strongly recommended that a blood filter is used when using a bowl from the affected lot numbers.

## 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
- Anaesthesia, directors of
- Anaesthetic nursing staff
- Anaesthetists
- Biomedical engineering staff
- Clinical perfusionists
- Operating department practitioners
- Outpatient theatre managers
- Outpatient theatre nurses
- Theatre managers
- Theatre nurses
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

## 6. CONTACTS:

Enquiries to the manufacturer/supplier should be addressed to:

Marco Mantovani  
Sorin Group Italia Srl  
Via Statale 12 Nord, 86  
41037 Mirandola (MO)  
ITALY

Tel: +39 0535 29942  
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Gloucester Business Park  
Gloucester GL3 4AH

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Fax: 01452 638 530

E-mail: [Mike.Brough@sorin.com](mailto:Mike.Brough@sorin.com)

Enquires to NIAIC should quote reference number MDEA(NI)2006/76 and be addressed to:

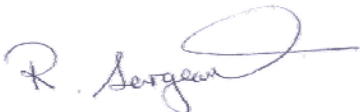
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Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
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## 7. FEEDBACK:

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*