Medical Device Incident Investigations: Recommendations

Syringe Pump, Smiths Medical Graseby 3300: Unauthorised access to locked syringe compartment

TGA reference: DIR15863

Both Smiths Medical and the Therapeutic Goods Administration have received a report which claimed that it is possible to forcibly open the locked syringe cover of the Graseby 3300 PCA Syringe Pump and access an installed syringe, without using the key to properly unlock the cover. The cover can then be returned to its closed and locked position without visibly damaging the pump or causing the pump to alarm. We have been able to duplicate such forcible access.

Smiths Medical is in the process of designing a modified syringe cover component that will reduce the opportunity to force open the cover. It is estimated that the modified syringe cover will be available to customers, in the form of an installation kit, during July 2007.

Until the modified locking cover has been installed, users are advised to carefully consider the circumstances in which the Graseby 3300 PCA Syringe Pumps will be used and, if it is judged that the likelihood and consequences of tampering represents a high risk, then consider utilising an alternative infusion device.

To implement and coordinate the fitting of the syringe cover installation kits, Smiths Medical will be issuing a Recall for Product Correction Letter to all affected customers in Australia and New Zealand once the installation kits are available.

Smiths Medical will provide installation instructions with the kits to enable Biomedical Engineers to fit the modified locking covers to any Graseby 3300 PCA Syringe Pumps in their facility. Smiths Medical can install the modification kits if this is more convenient or if the facility does not have a Biomedical Engineering function.

Smiths Medical Australasia will redesign and recall the cover locking mechanism in consultation with the Therapeutic Goods Administration.

For additional information please contact Smiths Medical Australasia Pty Ltd at:

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Samples for testing—Protocol for sending medical devices to the TGA for testing

Medical devices involved in an adverse event may be sent to the TGA for testing. The TGA accepts devices that are contaminated. The TGA can test or visually inspect all medical devices. There are some devices for which the TGA cannot do a complete examination as the equipment available for some of the tests is specific to the device manufacturer. The TGA will, however, test or examine the device and, if granted permission by the reporter, the device will be sent to the manufacturer for further testing. Analysis of the manufacturer's testing is required by the TGA as part of its investigation of the adverse event report.

It is important to keep the device after submitting a report until the IRIS has contacted you to say whether the device should be sent to the TGA or to the sponsor/manufacturer.

When sending medical devices to the TGA please follow these steps:

1. Clean the device as much as possible without destroying any evidence that you feel contributed to the adverse event.
2. All devices should be doubled-packaged in plastic bags designed for transport of bio-hazardous objects. The outer package must be clearly labelled with the contents and warnings if the device is contaminated.
3. If the device has sharp edges or components, such as suture needles, please pack these items into a sealed plastic container in addition to the plastic bags.
4. Medical devices should be sent to:

   The Coordinator Incident Report Investigation Scheme
   TGA
   Office of Devices, Blood and Tissues
   136 Narrabundah Lane
   Symonston ACT 2909

5. The TGA uses a courier for transporting medical devices. To use this courier service at the TGA's expense, please contact the coordinator on 1800 809 361.

Weighing Device—Skipper 175 and PWS 300 Weighing Device—Maintenance and servicing of these types of devices

The TGA has received a report of the failure of suspension components between a Skipper 175 and PWS 300 Weighing Device which resulted in an elderly patient falling a short distance to a bed.

While the cause of the device(s) failure has not been conclusively determined, it appears to be related to substandard servicing and/or components fitted by an unauthorised agent. For example:

- The Load cell had a 450mm cable instead of normal Promed 150mm cable.
- The suspension bolt for the load cell had been modified with a second hole for a locking pin.
- The pin used to lock the suspension bolt was of a soft metallic material instead of the usual hardened cell-lock pin supplied by Promed.
- A key ring had been used in place of the standard 'R' clip supplied by Promed.
- The guide bolt for the leg spreader actuator was not the standard one supplied by Promed.

Invacare, the supplier of this product, concluded that the devices involved in the incident had been 'serviced, modified and repaired' by parties not authorised by Invacare Australia and that substandard parts had been substituted.

Invacare have issued a Bulletin to all users warning that tampering and maintenance by unauthorised parties would invalidate any warranties and may make the device(s) unsafe.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT 01/10/2006 to 31/12/2006
Total Number Received: 278

Cause of Problem[1]	
Component Failure	14
Contamination	3
Design	25
Electrical	6
Inadequate Instructions	5
Labelling	5
Maintenance	6
Manufacture	28
Material/Formulation Deficiency	7
Mechanical	18
Not Device Related	23
Other	74
Packaging/Sterility	5
Quality Assurance	5
Unknown	72
Wear/Deterioration	17

Effect	
Death	16
Serious Injury	35
Temporary Injury	77
No Injury	150

Source Category	
Medical Administrator	6
Specialist	6
Nurse	21
Blood Bank	6
Hospital Supply Service	18
Other	10
Sponsor	160
Overseas Advice	0
Biomed Engineer	11
Para Medical	3
Patient/User	6
Dentist	0
Coroner	1

Result of Investigation	
Bulletin Article	4
Company Warned	1
Compliance Testing	2
No Further Action	74
Not Investigated[2]	136
Other	5
Problem Not Confirmed	10
Product Improvement	38
Recall/Hazard Alert	7
Safety Alert	4
User Education	7

Notes:

1. The problem causes are not mutually exclusive. For example, a material deficiency may have led to a mechanical malfunction or a biocompatibility problem.
2. Every report received by IRIS receives a risk analysis by the Scheme Coordinator and is discussed by a panel of technical and clinical professionals. In the case of reports that are "Not Investigated" the panel has made a decision that further investigation of the particular event is not necessary at that time. However, these reports are logged into the database for future reference and the trend of reports is monitored. In making their decision, the panel considers whether any similar reports have been received previously.