Medical Device Incident Investigations: Recommendations

Hazard Alert: Implex Ceramic Acetabular Cups (DIR 13749)

Zimmer Australia has issued a Hazard Alert following consultation with the TGA. Four Implex Ceramic Acetabular Cup fractures occurred within Implex's Investigational Device Exemption (IDE) study of this product in the United States. In three of the cases, the ceramic liner fractured prior to revision surgery. In a fourth case, the ceramic liner was retrieved at the time of revision surgery. An additional two liner fractures have been recorded in Australia.

Implex is currently investigating the potential causes of these device failures. All factors that may have contributed to the ceramic liner fracture and ceramic liner disassociation, solely or in combination with the respective position of these cups, are being assessed. It is presently believed that malposition of the cup, either in version and/or inclination, has led to stem neck impingement on the cup ceramic insert and subsequent insert dislocation and/or overloading.

A design change may be pending to increase the resistance to insert dislocation in cases of cups that are implanted in extreme malposition. As a result of these findings, Zimmer has elected to issue a Hazard Alert and stop distributing these products, pending the result of Implex's investigation and possible design enhancement of the products.

The products affected are shown in Table 1. Forty-five Australian patients have received these implants.

Table 1. Products subject to Zimmer's Hazard Alert on Implex Acetabular Cups

Zimmer Product Number	Implex Product Number	Description
99725704828	2-272-28481	Implex ceramic cup 28mm x 48mm
99725705028	2-272-28501	Implex ceramic cup 28mm x 50mm
99725705228	2-272-28521	Implex ceramic cup 28mm x 52mm
99725705428	2-272-28541	Implex ceramic cup 28mm x 54mm
99725705628	2-272-28561	Implex ceramic cup 28mm x 56mm
99725705828	2-272-28581	Implex ceramic cup 28mm x 58mm
99725706028	2-272-28601	Implex ceramic cup 28mm x 60mm
99725706228	2-272-28621	Implex ceramic cup 28mm x 62mm
99725706428	2-272-28641	Implex ceramic cup 28mm x 64mm

Recommendation

In light of this information, it is recommended that you review the management of your patients who have received an Implex Ceramic Cup. Zimmer sent a Hazard Alert letter to all surgeons who have implanted the cup. If you have not received this letter or need further information please contact Michael Schaffler, Operations Manager, Zimmer Australia, on 02 9950 5420.

Safety Alert: Patient monitors can interpret pacemaker pulses as normal heart rhythm (DIR 13705)

The TGA received a letter from the Queensland Coroner's Office about the death of a patient who was being monitored using a GE Medical Solar 8000 patient monitor. The patient's heart had stopped beating, but the monitor failed to alarm because it was interpreting the pulses from the patient's pacemaker as the patient's own heartbeat.

Several factors contributed to this event, notably:

- Only one form of monitoring was being used to alarm this patient's change in condition. In fact, the alarm of a respiratory sensor had been muted because it alarmed excessively.
- The monitor was being used to monitor the patient's heartbeat. This was the only life sign that was being used to monitor and alarm the patient's condition. After her heart valve surgery, the patient had also been fitted with a pacemaker to assist her recovery. The instructions for use of the patient monitor state that the monitor can interpret pacemaker pulses as the patient's normal heartbeat. This seems to be exactly what happened. When the patient's heart stopped, the pacemaker continued to operate, fooling the patient monitor. When the nurse next checked the patient's condition, it was too late.

The TGA warned about the use of only one form of monitoring in the *Australian Therapeutic Device Bulletin, No 33* (July 97). The warning stated that this practice was not recommended and that more than one form of monitoring — for example, heart rate AND oxygen saturation — should be used on all patients in acute areas such as emergency. Also, alarms should not be muted, particularly on patients in acute care areas. One of the purposes of this article is to restate that advice.

The coroner found that the monitor "contributed to the death" in that it didn't alarm because of the interference by the pacemaker. While this is mentioned in the manual for the monitor, the coroner observed that it is well buried within that manual. Therefore, it is also recommended that all personnel who use physiological monitors be made aware of these types of idiosyncrasies. This should be done at the time of their induction to areas of the hospital where this may be a factor in treating patients.

A Safety Alert by GE Medical has been distributed to all known users of the Solar 8000 patient monitors. The Safety Alert highlights the possibility of pacemaker spikes being interpreted as the patient's heart rhythm during a cardiac arrest.

Recommendations

1. It is recommended that multiple mode alarms are always employed for patient monitoring in acute areas.
2. If you are a user of Solar 8000 monitors ensure that you have received the Safety Alert about possible interference by pacemakers. Please ensure that all staff using the device are aware of the Safety Alert. If you require further information, please contact GE Medical Systems on 02 9316 3700.
3. It is important that all users of patient monitors are thoroughly acquainted with the instructions especially in regard to documented limitations.

Safety Alert: Potential for disconnection of Luer Slip Fittings (DIR 13741)

On 11 April 2003, Baxter Healthcare Corporation issued a Customer Advisory Letter warning of the potential for disconnection of Luer Slip Fittings.

In November/December 2000, the Infusion Nurses Society (INS) published practice criteria for all add-on infusion devices. These standards provide a framework for developing infusion policies and procedures in all practice settings. The standards apply **to all brands of Luer Slip Fittings**.

Protocols for use and frequency of change of add-on devices and junction securing devices should be in accordance with the manufacturer's guidelines. Add-on devices include stopcocks, extension sets, manifold sets, extension loops, solid cannula caps, injection/access ports, needles or needleless systems, and filters. All add-on devices should be of Luer lock design.

When add-on devices are used, they should be changed with each replacement of a catheter or administration set, or whenever the integrity of either product is compromised. Tape should not be used as the sole means of securing junctions. Baxter has previously cautioned the clinical community to use only Luer lock adapters for central venous catheters, arterial lines or other critical applications. Package labelling is being enhanced in the following manner to reinforce this caution:

> **WARNING: Do not use Luer slip adapters for central venous catheters, arterial lines or other critical applications where accidental disconnection could result in serious patient injury or death.**

For information about the INS standards, please see the *Journal of Intravenous Nursing: Infusion Nursing Standards of Practice, Supplement 10, November/December 2000*. For additional clinical education, please refer to Baxter's online CE program website <www.baxter.com/ce-program> that offers accredited programs on the administration of IV therapy using peripheral lines, midline and central line catheters.

Recommendation

Please consider a review, including consultation with clinical leaders in medicine and nursing, to determine your institution's needs for and practices involving the use of Luer slip (non-locking) friction fit connectors.

ResMed Sullivan VPAP II and VPAP II ST

The TGA has been informed that these devices are widely used as life support units, especially for elderly patients. In one reported case, a patient — who is totally dependent on the device — complained about the lack of a power backup system in case of power failure. The patient claims that he would die if the machine stopped. In another report, hospital staff stated that the device had been used as a life support patient ventilator when it stopped working due to a motor bearing failure. In that case, the patient was hand ventilated until a replacement unit was obtained.

The Sullivan VPAP II and VPAP II ST manufactured by ResMed P/L are non-continuous ventilators intended to augment the ventilation of patients who have restrictive or obstructive respiratory disorders and require non-continuous ventilator support. Examples of such respiratory disorders are obstructive sleep apnoea, chronic obstructive pulmonary disease, neuromuscular and chest wall diseases. The Clinical and Operating Manuals state that these devices are not intended to be used as life support ventilators. They may stop operating with power failure or if a fault occurs in the product.

Recommendations

The TGA emphasises that the use of ResMed Sullivan VPAP II and VPAP II ST ventilators for life support is in breach of the manufacturer's recommendation and may lead to a serious adverse event. The units lack appropriate alarms and backup modes normally required for life supporting patient ventilators.

'Single leg separation' found in recently explanted Bjork-Shiley Prosthetic Heart Valve

The TGA has received a recently explanted Bjork-Shiley CC70^0 21mm Aortic Prosthetic Heart Valve for examination. Scanning Electron Microscopy revealed a crack on one of the outlet struts. This is indicative of an active 'single leg separation' process. Similar cracks in other heart valves of this type, if not explanted, resulted in disc escape and subsequent death of the patient.

In Australia, fifty-one of the Bjork-Shiley CC70^0 21 mm prosthetic heart valves have been implanted and, until now, only one fracture of a valve of this size was found (in 1983).

Regulatory action on this issue took place many years ago and this type of valve is no longer supplied. However many patients continue to live with this device *in situ*. These two cases are of particular interest because the majority of fractures have occurred with larger diameter valves. It is important to continue to examine ALL explanted Bjork-Shiley CC prosthetic heart valves in order to update the risk assessment for the remaining recipient population.

Recommendation

Please continue to report to the TGA any adverse events associated with this or any other device. In any case, but particularly in the case of devices such as heart valves, we request that you send the device to the TGA for initial examination. After initial examination, the TGA can either return the device or send it on to the manufacturer for further analysis.

SYNC/NON-SYNC behaviour of Heartstream M4735A Defibrillator (DIR 13695)

The TGA has received a report stating that a Heartstream M4735A Monitor/Defibrillator failed to fire as expected. When the operators noticed that the unit was in SYNC mode they attempted to reset to NON-SYNC mode by turning the power off and then on again. For many monitor/defibrillators on the market, turning the power off and then on again will return the device to default settings (that is, SYNC mode will be reset to OFF). The Heartstream M4735A Monitor/ Defibrillator does not behave in this way. This defibrillator has been deliberately designed so that once SYNC mode is selected, it will maintain this setting when power is removed or even if the internal battery is removed for up to two minutes. This feature is to allow clinicians to disconnect mains power or change the battery without losing the setting for SYNC mode. This is considered to be a safety feature, particularly in a cardiac clinic where synchronised cardioversion is routinely performed, and is promoted as such by the manufacturer and the Australian supplier, Philips.

When used in manual mode the M4735A Heartstream Monitor/ Defibrillator can be used in SYNC Mode or NON-SYNC Mode. Once SYNC mode has been selected during a procedure, it remains on until deliberately turned off unless all power is removed for at least two minutes. The mode is always clearly displayed on the visual display and the mode can be switched by pressing a button on the front panel (indicated by a label directly above it on the display).

It is generally believed that turning the power off and then on again will return any electronic device to its default settings (in this case that SYNC mode on the Heartstream defibrillator will be reset to OFF). There is the possibility that in an emergency, if operators are not aware of the particular behaviour of the Heartstream M4735A, this could lead to serious consequences.

As a result of this investigation Philips will issue a Safety Alert to:

1. Warn users about the particular behaviour of the M4735A compared with other defibrillator/monitors.
2. Advise that where users prefer SYNC mode to be turned OFF after each shock, they should refer to Section 10-12 of the Configuration Instructions in the User Guide for the M4735A.
3. Explain how to disable the SYNC mode from the front panel (refer to Section 7-7 of the Users Manual).

Recommendations

1. Please note the particular behaviour of the Heartstream M4735A when being switched off and on and ensure that all users in your facility are aware of this behaviour.
2. Users can contact Rolfe Stoekle from Philips on 03 9271 3524 for additional information.

The TGA emphasises that there is no inherent fault in the Heartstream M4735A, rather that it behaves slightly differently to other monitor/defibrillators.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT 01/01/2003 to 31/03/2003

Total Number Received: 114

Cause of Problem[1]		**Effect**		**Result of Investigation**	
Biocompatibility	11	Death	3	Company Warned	2
Component Failure	17	Serious Injury	22	Compliance Testing	2
Contamination	7	Temporary Injury	14	No Further Action	39
Design	12	No Injury	75	Not Investigated[2]	39
Diagnostic Inaccuracy	2	**Source Category**		Other	4
Electrical	5	Medical Administrator	2	Problem Not Confirmed	9
Inadequate Instructions	4	Specialist	10	Product Improvement	9
Labelling	2	General Practitioner	1	Recall/Hazard Alert	8
Maintenance	1	Coroner	3	Refer to GMP	5
Manufacture	16	Nurse	11	Refer to Surveillance	1
Material/Formulation Deficiency	26	Blood Bank	21	Safety Alert	8
Mechanical	11	Hospital Supply Service	14	User Education	6
Not Device Related	6	Other	13		
Other	3	Sponsor	29		
Quality Assurance	4	Overseas Advice	1		
Unknown	14	Biomed Engineer	9		
Wear/Deterioration	6				

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.