



December 2009

A patient **Safety Notice** strongly advises the implementation of particular recommendations or solutions to improve quality and safety.

We recommend you inform:

- Supply Department
- Biomedical Engineering
- Safety and Quality Unit
- Clinical Departmental Managers

Therapeutic Goods Administration (TGA) Recalls

Summary for December 2009

The established process for TGA medical device recalls/product corrections is for the manufacturer/sponsor to dispatch letters to the relevant service providers within two working days of the recall date. If affected, your health service will have received a letter from the manufacturer/sponsor advising of the recall.

Class I – Class I defects are potentially life-threatening or could cause a serious risk to health.

Class II – Class II defects could cause illness or mistreatment, but are not Class I.

Class III – Class III defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

Class I & II recalls are considered to be safety related recalls.

This Safety Notice is provided to reinforce the TGA process. It contains selected medical device hospital and retail level recalls/product corrections for your implementation, if relevant.

Persons receiving this notice should **NOT** take any further action unless the affected goods are supplied to/in use in their health service

FOR SA HEALTH STAFF ONLY

Due date for response to the Department of Health is 15th March, 2010.

ALERTS

Servo Ventilator 300/300A (SV300) and Servo Ventilator 900C/D/E (SV900) **The product is not defective and is not being recalled**

ARTG Number 162468
Reference: RC-2009-RN-01013-3
Date Agreed: 10/12/2009
Company: Maquet Australia Pty Ltd
Reason A negative pressure in the breathing system (eg generated by an improper application of closed system suctioning CSS), may impair the functionality of the pressure transducers in the ventilator. Such a pressure is created when the suctioning flow exceeds the flow delivered to the patient by the ventilator. A negative pressure of -100 cmH₂O, or more can damage the pressure transducers in the ventilator, in the unlikely event of a failure of both transducers simultaneously, the ventilator may deliver a high positive pressure.
If both pressure transducers in the ventilator are damaged simultaneously the ventilator may deliver a high positive pressure which can lead to injury or death (refer to attachment).
Sites Affected: (Only those sites listed are required take appropriate action)
All sites

COGNIS® cardiac resynchronisation therapy defibrillators (CRT-Ds) and TELIGEN® implantable cardioverter defibrillators (ICDs) **COGNIS® (CRT-Ds) Model numbers - N106 (ARTG 154034) & N107 (ARTG 154033);** **TELIGEN® (ICDs Model numbers - E102 (ARTG 154037) & E110 (ARTG 154039)**

Reference: RC-2009-RN-00981-3
Date Agreed: 1/12/2009
Company: Guidant Australia Pty Ltd
Phone: 02 8063 8149 - Jan Murton
Reason: Implanted devices may encounter sufficient mechanical stress to weaken the bond between the header and case when positioned subpectorally (refer to attachment).
Affected Sites: (Only those sites listed are required take appropriate action)
Ashford Community Hospital, Adelaide Community Healthcare, Flinders Private Hospital, Queen Elizabeth Hospital, Royal Adelaide Hospital, Wakefield Street Hospital.

RECALL CLASS I

Philips Avalon Fetal Monitors FM20, FM30, FM40, FM50

Reference: RC-2009-RN-00978-3
ARTG Number 99202
Date Agreed: 30/11/2009
Company: Philips Electronics Australia Ltd
Phone: 1800 251 400 - Philip's Customer Care Centre
Reason: An update to the Instructions for Use due to increased complaints of inaccurate ultrasound-derived foetal heart rate readings
Sites Affected: (Only those sites listed are required take appropriate action)
 Women's & Children's Hospital, Flinders Medical Centre, Lyell McEwin Health Service, Burnside War Memorial Hospital, North Eastern Community Hospital, Surgical And Medical Supplies.

CBC II Blood Conservation Units

ARTG Number 140544
Reference: RC-2009-RN-00938-3
Date Agreed: 27/11/2009
Company: Stryker Australia Pty Ltd
Phone: 02 9467 1276 - Kim Collings
Reason: There is a potential that the package pouch could have a pinhole, weakened seal, or an open seal that will result in the product not being sterile.
Sites Affected: (Only those sites listed are required take appropriate action)
 Calvary Wakefield Hospital, Sportsmed SA, St Andrews Private Hospital, Stirling District Hospital.

Product Description	Catalogue No	Lot No
CBCII 1/8 DRAIN (PK6)	225414000	All lots between 07305012 and 09192012
CBCII 1/4 DRAIN	225416000	
CBC II 3/16 DRAIN	225426000	
CBCII W/DBLE TROCAR 1/8	225028614	
CBCII W/DBLE TROCAR 3/16	225028626	
CBCII W/Q.DISC.1/8 DRAIN	225028914	

CLASS I (CONT)

Clinac C-series and Novalis Tx with electron beams (linear accelerator system used in radiotherapy. Selected serial numbers.

ARTG Number 116839
Reference: RC-2009-RN-00976-3
Date Agreed: 14/12/2009
Company: Varian Medical Systems Australasia Pty Ltd
Phone: 02 9485 0122 - John Wyndham
Reason: An anomaly was discovered in which, under certain circumstances of control circuit adjustments and component failure, a C-Series Clinac can beam on with an asymmetric electron beam, which is undetected by the interlocks intended to prevent it.

Sites Affected: (Only those sites listed are required take appropriate action)
 Lyell McEwin Hospital, Royal Adelaide Hospital.

H14020	H14020	H14020	H14022	H14023	H14023	H14023	H14023	H14023
H14071	H14072	H14073	H14075	H14076	H14077	H14078	H14079	H14081
H14084	H27032	H27036	H27066	H27103	H27105	H27105	H27112	H27124
H27129	H27145	H27149	H27153	H27158	H27159	H27163	H27164	H27185
H271877	H272004	H272091	H272154	H272251	H272434	H272493	H272828	H272889
H272922	H273027	H273072	H273102	H273103	H273107	H290335	H291054	H291098
H291114	H291160	H291163	H291164	H291165	H291191	H291212	H291259	H291260
H291261	H291262	H293422	H293442	H293512	H293561	H293620	H293666	H293724
H293817	H293843	H293847	H293850	H293968	H293970	H294017	H294022	H294062
H294065	H294175	H294232	H294409					

CLASS II

Various XCellerate 4:1 Ceramic Cutting Blocks Scorpio Ceramic 4-in1 Cutting Blocks (Catalogue Nos 8000-0003 to 8000-0013) Duracon Ceramic 4-in1 Cutting Blocks (Catalogue No 8000-7010 to 8000-7060)

ARTG number 112787
Reference: RC-2009-RN-01020-3
Date Agreed: 17/12/2009
Company: Stryker Australia Pty Ltd
Phone: 1800 803 601 - Lachlan McKenzie
Reason: The ceramic guide rails, within the XCellerate 4:1 Ceramic Cutting Blocks, may fracture and become displaced from the block. World wide failure rate is 0.003%. In failure mode, small fragments may contaminate the wound .

Affected Sites: (Only those sites listed are required take appropriate action)
 Mount Gambier Hospital.

CLASS II (CONT)

Various theatre lights manufactured by Maquet AS France

MAQUET Blue 130, MAQUET Hanaulux 2004-2005, MAQUET Hanaulux 3004-3005,
MAQUET ALM XTEN

Reference: RC-2009-RN-00765-3
Date Agreed: 2/10/2009
Company: Maquet Australia Pty Ltd
Phone: 0434 655 039 - Rick Casey
Reason: A potential crack may develop in the welding of the swing arm of some theatre lights that were supplied in Australia between 2000 and 2006 (refer to attachment).
Affected Sites: (Only those sites listed are required take appropriate action)
The Queen Elizabeth Hospital, Lyell McEwin Health Service.

Alaris Gateway Workstation (AGW), Pole clamp

ARTG Number 130770
Reference: RC-2009-RN-00996-3
Date Agreed: 7/12/2009
Company: CareFusion Australia 316 Pty Ltd
Phone: 1800 110 511 - Customer Service
Reason: Small number of reports of the turn screw becoming permanently bent resulting in the release of the secure hold of the Alaris Gateway Workstation.
Affected Sites: (Only those sites listed are required take appropriate action)
Child Youth and Women's Health Service.

Symbia S & T radiological imaging systems

ARTG Numbers 123883 & 141951
Reference: RC-2009-RN-01009-3
Date Agreed: 17/12/2009
Company: Siemens Ltd
Phone: 1800 227 587 - John Selakovic
Reason: A small number of hand controllers are missing a resistor switch and the absence of the switch may lead to an unintended system motion during camera set up activities.
Affected Sites: (Only those sites listed are required take appropriate action)
Queen Elizabeth Hospital, Dr Jones and Partners - St Andrews Hospital.

CLASS II (CONT)

ARCHITECT HIV Ag/Ab Combo Calibrator. An in vitro diagnostic medical device. List number: 4J27-01, Lot number 73507HN00

ARTG Number 119834
Reference: RC-2009-RN-01039-3
Date Agreed: 17/12/2009
Company: Abbott Australasia Pty Ltd Diagnostic Division
Phone: 1800 816 696 - Abbott Customer Support
Reason: The calibrator values for this lot number decrease over time, leading to invalid calibrations and out-of-range high controls.
Affected Sites: (Only those sites listed are required take appropriate action)
SA Pathology.

Eclipse 1.5T MRI System Catalogue number 781230

ARTG Number 98887
Reference: RC-2009-RN-01055-3
Date Agreed: 21/12/2009
Company: Philips Electronics Australia Ltd
Phone: 1800 251 400 Philips Customer Care
Reason: The RF connector block on the tabletop has the potential to smoke and ignite during scanning due to a combination of arcing of electrical components below the connector and the flame rating of the connector block material.
Affected Sites: (Only those sites listed are required take appropriate action)
Benson Radiology.

Guider Sofftip XF Guide Catheters

ARTG Number 146034
Reference: RC-2009-RN-01068-3
Date Agreed: 23/12/2009
Company: Boston Scientific Pty Ltd
Phone: 02 8063 8147 - Dana Leydon
Reason: Following a Safety Alert regarding catheter material degradation if not stored correctly (away from light), the company has introduced new labelling of the devices and is recalling current stock for replacement with newly labelled stock.
Affected Sites: (Only those sites listed are required take appropriate action)
Royal Adelaide Hospital.

CLASS III

Unicel DxH 800 Coulter Cellular Analysis System An in vitro diagnostic medical device (IVD)

Reference: RC-2009-RN-01052-3C
Date Agreed: 17/12/2009
Company: Beckman Coulter Australia Pty Ltd
Phone: 1800 060 881 - Beckman Coulter Technical Centre
Reason: Beckman Coulter have identified three transmission problems with the Unicel DxH 800 Coulter Cellular Analysis System when they are interfaced with a Laboratory Information System (LIS).
Sites Affected: (Only those sites listed are required take appropriate action)
SA Pathology.