



November 2008

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 October 2008

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.

## Class I Recall

### **Philips BV Pulsera and Endura Rel 2. X-Ray Systems**

**(ARTG number 98556)**

**(REFERENCE: RN-2008-0785)**

**Date:** 26/9/2008

**Reason:** 1. Due to reliability issues with the stand-trolley cable, communication between the stand and trolley may not be optimal. This may result in intermittent incorrect functioning of the system.

2. When the extended C-arm rotation is fitted, the rotation brake does not always function properly. The brake functions well if the C-arm is rotated to its maximum position.

**Further information:** Philips Electronics Australia Ltd, 1800 251 400 Philips Customer Care Centre.

### **Medtronic CareLink Remote Patient Monitor 2490C, when used with patients that have certain implantable defibrillators with OptiVol**

**CareAlerts (Concerto CRT-D, Virtuoso DR & Virtuoso VR)**

**(ARTG number 133762)**

**(REFERENCE: RN-2008-0844)**

**Date:** 15/10/2008

**Reason:** The CareLink software may not detect when a patient's OptiVol fluid index crosses a clinician-determined threshold, which is an indicator of heart condition.

**Further information:** Medtronic Australasia Pty Ltd, 02 9857 9000 – Arianne Lee.

## Class II Recall

### **Oxylog 3000 Emergency Transport Ventilator**

**(ARTG number 116957)**

**(REFERENCE: RN-2008-0788)**

**Date:** 30/9/2008

**Reason:** Oxylog 3000 equipped with software version 1.10, under specific conditions, may experience an interruption of ventilation for a time period of approximately 5 seconds.

**Further information:** Draeger Medical Australia Pty Ltd, 03 9244 7238 – Jim Collins.

## Class II Recall (cont.)

### Wizard Dual Port Low Profile Replacement Gastrostomy Device (specific lot numbers)

(ARTG number 141583)

(REFERENCE: RN-2008-0799)

Date: 9/10/2008

**Reason:** Potential for valve leaflet fracture, which may cause leakage from the device of gastric contents and feeding solutions.

**Further information:** Bard Australia Pty Ltd, 1800 257 232 – Bard Customer Service

Size	16FR						
Product code	00202W	00210W	00215W				
Lot numbers	43ARA030	43KNA059	43BQA188				
	43HPA051		43DPA216				
	43JQA028		43HQA035				
	43LPA112		43JPA045				
	HURCA095		HURA1339				
	HURF0486		HURC9895				
			HURG1456				
Size	18FR						
Product code	00221W	00222W	00223W	00224W	00225W		
Lot numbers	43HPA061	HURF0511	43BQA054	43APA046	43BPA206		
			43EPA060	43GPA163	43HPA229R		
			43GQA037	43HPA064			
			43JPA051	43IQA036			
			43KQA045	43JQA033			
			43LQA047				
Size	20FR						
Product code	00203W	00204W	00205W	00206W	00212W	00213W	00214W
Lot numbers	43GQA034	43BOA039	43BQA185	43EQA052	43APA040	43BQA187	43APA042
		43BQA046	43INA036		43DPA049	43EOA048	43DPA051
		43DPA208	43IQA029		43EPA050	43FPA178	43EPA052
		43KQA030			43EQA055	43GPA236R	43GPA152
		43LNA055			43GOA037	43GQA035	43IOA047
					43GPA211R	43IQA032	43IPA049
					43HQA032	43JPA043	43IQA033
					43INA041	HURD1929	43KQA038
					43LQA038	HURE2907	43LQA040
					HURA1329	HURF0500	HURA1337
							HURB2433
Size	24FR						
Product code	00216W	00217W	00218W	00219W			
Lot numbers	43LNA059	43CQA233	43APA043	43EPA057			
		43DPA218	43DPA220				
		43IOA050	43EPA056				
		43LQA042	43EQA207				
			43HPA060				
			43KOA026				

## Class II Recall (cont.)

**Access Immunoassay Systems Assay Protocol File (APF)  
Software versions for: Access, Access 2, SYNCHRON LX I 725, and  
Unicel Dx C 600i systems (implemented April 2007).  
An in vitro diagnostic medical device (IVD)**

**(ARTG number )**

**(REFERENCE: RN-2008-0807)**

**Date:** 3/10/2008

**Reason:** As a result of a software problem, erroneous results may be generated when the instrument is executing the Total BhCG P-command.

**Further information:** Beckman Coulter Australia Pty Ltd, 1800 060 881 – Beckman Coulter Technical Support.

## **VIGILANCE II Cardiac Output Monitor**

**Model Nos. VIG2E & VIG2**

**(ARTG number 142756)**

**(REFERENCE: RN-2008-0811)**

**Date:** 3/10/2008

**Reason:** Use of Intermittent Cardiac Output (ICO) using the bolus thermodilution method, along with an in-line temperature probe, may lead to an error in the ICO measurement.

**Further information:** Edwards Lifesciences Pty Ltd, 1800 222 602 – Edwards Customer Service.

## **iPTH Kit Lot 138 used with ADVIA Centaur and ADVIA Centaur CP**

**An in vitro diagnostic medical device (IVD)**

**(ARTG number )**

**(REFERENCE: RN-2008-0815)**

**Date:** 7/10/2008

**Reason:** Imprecision and a low bias observed with iPTH.

**Further information:** Siemens Healthcare Diagnostics Pty Ltd, 1800 358 030 - Mr Vince Chiera

## **Excelsior SL-10 Microcatheter (straight), Various lot numbers**

**(ARTG number 143033)**

**(REFERENCE: RN-2008-0816)**

**Date:** 10/10/2008

**Reason:** Product packaging fails product specification requirements for maintaining its sterile barrier through distribution and shelf life.

**Further information:** Boston Scientific Pty Ltd – Local Sales Representative.

## Class II Recall (cont.)

### DLP Pericardial/Intracardiac Sump 20 Fr.

**Model # 12112, Lot # 2006100305**

**(ARTG number 123150)**

**(REFERENCE: RN-2008-0817)**

**Date:** 8/10/2008

**Reason:** The sump tip assembly may separate from the tubing.

**Further information:** Medtronic Australasia Pty Ltd – Local Sales Representative.

### Stryker System 6 and Cordless Driver III Hand pieces

**(ARTG number 139725, 140430 & 140431)**

**(REFERENCE: RN-2008-0831)**

**Date:** 15/10/2008

**Reason:** There is a potential for the handpieces to continually run even when the trigger is not depressed.

**Further information:** Stryker Australia Pty Ltd, 1800 667 558, Alison Pratt.

Product Name, Part Numbers, Serial Numbers Affected			
4300-000-000	Cordless Driver 3	0723505023	0804326503
6203-000-000	System 6 Single Trigger Rotary Hand piece	0614504853	0825902483
6205-000-000	System 6 Dual Trigger Rotary Hand piece	0615001103	0826001573
6206-000-000	System 6 Reciprocating Saw	0613702313	0826201253
6207-000-000	System 6 Sternum Saw	0613902933	0826101223
6208-000-000	System 6 Sagittal Saw	0615000953	0826200893
6209-000-000	System 6 Precision Saw	0620602123	0825317713

### HMRS Humeral Head Fixed and Distal Humerus Cone

**(modular components used in replacement of bone segments)**

**Product Code: 64600001 and 64600003**

**(ARTG number 128447)**

**(REFERENCE: RN-2008-0855)**

**Date:** 22/10/2008

**Reason:** The female taper of the Humeral Distal Cone may not achieve taper locking due to insufficient clearance beyond the taper.

**Further information:** Stryker Australia Pty Ltd, 0419 680 452 – Jacinta Josey.

### TruPath™ Biopsy Device and easy Core™ Biopsy Device

**(ARTG number 119407)**

**(REFERENCE: RN-2008-0857)**

**Date:** 20/10/2008

**Reason:** A limited number of complaints have been received related to difficulty cocking or arming the cannula latch on the Biopsy Device. This difficulty may result in an inability to use the device.

**Further information:** Boston Scientific Pty Ltd, 02 8063 8150 Susana Diaz.

## Class II Recall (cont.)

### **Arrow International Peripherally Inserted Central Venous Catheter (PICC lines)**

**PC-01351-TW, All lot numbers**

**(ARTG number 148782)**

**(REFERENCE: RN-2008-0867)**

**Date:** 24/10/2008

**Reason:** Current Instructions For Use (IFU) are being replaced with an updated version which describe in greater detail the process to be followed when trimming and inserting PICC catheters with integral placement wire, noting that trimming of the catheter should be avoided where possible.

**Further information:** The Mayo Group International Pty Ltd, 02 8337 7942 – Mr Geoff Braid.

### **ARJO Maxi Sky 600 V4 and V4i (patient lift) with Infra-Red Hand Control**

**(ARTG number 138041)**

**(REFERENCE: RN-2008-0876)**

**Date:** 24/10/2008

**Reason:** There is potential for the infra-red system to be difficult to operate, or to create uncontrolled movement of the ceiling lift, due to poor sensitivity to control signals.

**Further information:** Huntleigh Healthcare Pty Ltd, 1800 072 040 – David Henry.

### **Cordis Savvy LONG PTA Dilation Catheter**

**Product code 436-3022L**

**Lot number 50005346**

**(ARTG number 141082)**

**(REFERENCE: RN-2008-0888)**

**Date:** 28/10/2008

**Reason:** The labelling on the inner pouch is incorrect in relation to expanded balloon size and shaft diameter. The labelling of the outer carton is correct.

**Further information:** Johnson & Johnson Medical Pty Ltd, 1800 257 210 Richard Tanner.

### **Nutrex Research Lipo 6 liquid capsules**

**Batch 10001277**

**Expiry date 09/10**

**(REFERENCE: RN- 2008-0739)**

**Date:** 2/10/2008

**Reason:** Traces of yohimbine have been found in some bottles of this product

**Further information:** Export Corporation (trading as Nutrition Systems) - Customer Service 1300 883 523