



July 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 July 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.

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

## CLASS 1 RECALL

### Various Absorbable Sutures

**MONOCRYL\* (poliglecaprone 25) Suture Item Code: Y911G; Lot APZ480**

ARTG Number: 1381914

**Coated VICRYL\* (polyglactin 910) Suture Item Code J643H; Lot AP2528**

ARTG Number: 141405

**Coated VICRYL\* Plus Antibacterial (polyglactin 910) Suture  
Item code VCP105G Lot AP2507**

ARTG Number: 132034

**REFERENCE:** RC-2009-RN-00101-3

**DATE:** 9/02/2009

**COMPANY:** Johnson & Johnson Medical Pty Ltd

**PHONE:** 1800 257 210 - Mr Craig Bell

**REASON:** Sterility of the products cannot be assured due to a failure in the sterilisation process. Lack of sterility could potentially lead to infection and other serious patient consequences.

**Affected Sites:** (Only those sites listed are required take appropriate action)

- Repatriation General Hospital
- Ashford Hospital

## CLASS II RECALL

**Calibration packs for the ABL77 blood gas analysers**

**An in vitro diagnostic medical device (IVD) Part: 944-069**

**Lot Numbers: 32439, 32688 and 34151**

**ARTG Number:** -

**REFERENCE:** RC-2009-RN-00509-3

**DATE:** 2/07/2009

**COMPANY:** Radiometer Pacific Pty Ltd

**PHONE:** 1800 247 254 - Carolyn Sloman

**REASON:** Calcium may precipitate out of the Cal Pack Cal 1 solution. This would cause a reduction in the Calcium concentration in the solution which can affect the accuracy of the calibration value thereby impacting Quality Control and patient results for ionized calcium and, to a lesser extent, the pH and PCO<sub>2</sub> calibration values.

**AFFECTED SITES:** (Only those sites listed are required take appropriate action)

- Royal Adelaide Hospital

## CLASS II RECALL (cont)

### Icelock air expulsion valve (for lower limb prosthesis)

**Part number L-551000 ; Batch number CO081010**

**ARTG Number:** 41295

**REFERENCE:** RC-2009-RN-00512-3

**DATE:** 03/07/2009

**COMPANY:** Ossur Asia-Pacific

**PHONE:** 02 9360 9206 – Harvey Blackney

**REASON:** The L-551000 one-way air expulsion valve may fail if excessively high pressures are applied to the valve

**Affected Sites:** (Only those sites listed are required take appropriate action)

- Royal Adelaide Hospital

### ApexPro Telemetry Systems running software version 3.9 or earlier

**ARTG Number:** 118986

**REFERENCE:** RC-2009-RN-00549-3

**DATE AGREED:** 15/07/2009

**COMPANY:** GE Healthcare Australia Pty Ltd

**PHONE:** 1800 659 465 - GE Customer Care

**REASON:** The Operators Manual is being updated to correct and improve specific information relating to alarms and messages for SpO2 monitoring that may impact patient safety.

**Affected Sites:** (Only those sites listed are required take appropriate action)

- Flinders Medical Centre
- Lyell McEwin Health Service
- The Queen Elizabeth Hospital

### Staphylect Plus test kits - An *in vitro* diagnostic medical device (IVD)

**Pack numbers: DR0850M, DR0850B, DR0851Y**

**Batches: J539110, J577910, J577920, J591710, J610610, J610620, J652610, J669310.**

**ARTG Number:** –

**REFERENCE:** RC-2009-RN-00570-3

**DATE:** 27/07/2009

**COMPANY:** Oxoid Australia Pty Ltd

**PHONE:** 1800 331 163 - Peter Traynor

**REASON:** Technical investigation confirmed that the above lots may give false positives with some non-*Staph. aureus* strains

**Affected Sites:** (Only those sites listed are required take appropriate action)

- SA Pathology - Frome Road, and Wallaroo

**LeVeen™ Needle Electrodes – 5.0cm (for tissue ablation)  
Catalog numbers 6216 (5.0cm/15) and 6217 (5.0cm/25)  
Selected lots only (refer to table)**

**ARTG Number:** 119371

**REFERENCE:** RC-2009-RN-00517-3

**DATE:** 3/07/2009

**COMPANY:** Boston Scientific Pty Ltd

**PHONE:** 02 8063 8150 - Susana Diaz

**REASON:** During a procedure, the umbrella of the LeVeen™ Needle Electrode – 5.0cm may become detached from the core wire

**Affected Sites:** (Only those sites listed are required take appropriate action)

- Flinders Medical Centre

Product Description	Material Number	Catalog Number	Lot/Batch Number				
LeVeen™ Needle Electrode – 5.0cm/15	M001262160	6216	8745076	8745077	8745078	8745082	8745083
			8764662	8764663	8840136	8840210	8888632
			8922046	8922047	8922048	8925499	8946944
			8952359	8960112	8991516	9007921	9023847
			9051903	9063250	9080980	9103385	9103712
			9103713	9103714	9135758	9153911	9160547
			9275203	9288929	9300199	9303597	9406392
			9447228	9464347	9484064	9502208	9516123
			9591056	9629225	9643197	9659590	9708545
			9727738	9763201	9776097	9783671	11001461
			11005784	11034758	11042785	11091132	11114016
			11128377	11128379	11178425	11203868	11230657
			11356155	11403788	11440970	11460060	11551315
			11580328	11620899	11711276	11766589	11851200
			11881851	11900344	11916630	11931597	11943359
			11947005	12324021	12450298	12517661	12621268
LeVeen™ Needle Electrode – 5.0cm/25	M001262170	6217	8839481	8900349	9043740	9084603	9296400
			9300554	9442864	9531903	9569178	9707800
			9746026	9787308	11182329	11203869	11350192
			11403787	11518357	11559944	12219051	12475134