



August 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 July 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

COLLEAGUE Triple Channel Mono, CX and CXE Volumetric Infusion Pumps - Baxter Healthcare Pty Ltd - Product Codes: 2M8163CX and 2M9163CXE (ARTG number 128345)

(Reference: RN-2008-0522)

Date: 16/07/2008

Reason: Processing anomaly related to a buffer overflow condition, which could cause the triple channel pump to stop infusing. Under certain circumstances, this anomaly could occur in COLLEAGUE triple channel pumps with software version(s) 5.07, 6.12 or 6.13.90. **Please note: This is the second phase of an upgrade to the Colleague Triple Channel Pumps (Ref: RN 2007-0679 and RN 2007-0440). All hospitals previously involved have already been contacted.**

Further information: 1300 789 646 Baxter Customer Service

BD 60mL Luer-Lok Syringe, Catalogue number 309653

Please note: The Sponsor will contact all affected customers by phone and letter **(ARTG No: 118885)**

(Reference: RN-2008-0531)

Date: 17/07/2008

Reason: Individual unit package seal integrity (and resulting product sterility) can be adversely affected when the product is exposed to low pressure experienced at high altitudes (eg: during product shipping)

Further information: Becton Dickinson Pty Ltd, Melinda Serrano BD - 02 8875 7045

5224046	6117443	7130060
5224048	6117455	7156617
5229834	6188660	7152410
5229837	6188679	7163949
5229841	6219769	7187474
5243769	6236645	7213321
5251728	6251336	7214293
5256213	6257669	7242556
5279583	6305344	7242615
5291060	6317874	7271031
5318939	6356083	7276553
5325121	6356087	7298535
6019961	6361694	7316693
6019964	6361715	7298499
6060918	7025255	7333380
6067149	7025321	7334154
6067155	7025259	7334172
6090126	7025300	7334175
6090132	7025313	8031133
6096034	7060416	8058896
6117418	7124914	8072414
6117428	7124933	
6117430	7130058	
6117442	7142097	



Class I Recall (cont.)

HeartStart MRx Defibrillators, Philips M3535A / M3536A Philips Electronics Australia Ltd Various serial numbers

(ARTG number 95661)

(Reference: RN-2008-0534)

Date: 18/07/2008

Reason: Defective memory card may cause spontaneous restart, delayed start, or errors during use.

Further information: Philips Customer Care Centre 1800 251 400

Serial nos.	US00324835, US00324836	US00324908, US00324909
US00210783	US00324837, US00324838	US00324910, US00324911
US00316930	US00324841, US00324842	US00324912, US00324913
US00318057	US00324843, US00324844	US00324914, US00324915
US00324642, US00324645	US00324845, US00324847	US00324916, US00324917
US00324646, US00324680	US00324848, US00324849	US00324918, US00324919
US00324707, US00324712	US00324850, US00324851	US00324920, US00324921
US00324713, US00324826	US00324898, US00324899	US00324922, US00324923
US00324827, US00324828	US00324900, US00324901	US00324924, US00324925
US00324829, US00324830	US00324902, US00324903	
US00324831, US00324832	US00324904, US00324905	
US00324833, US00324834	US00324906, US00324907	

Argyle Suction Catheter Catalogue no 1180-851121, Lot 08E622E, Expiry May-2013

(ARTG number 138491)

(REFERENCE: RN-2008-0562)

Date: 31/07/2008

Reason: One lot of Argyle Suction Catheters may have pinholes in the packaging potentially compromising sterility of the device.

Further information: Mallinckrodt (A Division of Tyco Healthcare Pty Ltd) 1800 252 467 -

Class II Recalls

Triglyceride Reagent (REF 09580156, PN B01-4133-01) Lots 075393, 081324, 086564, 095939, 102610 and 105357

(Reference: RN-2008-0477)

Date: 1/7/2008

Reason: Triglyceride levels may be underestimated due to the reagent exhibiting a decrease of the upper limit of the linear range stated in the Instructions For Use (IFU)

Further information: Siemens Medical Solutions Diagnostics Pty Ltd, Technical Support Centre 1800 358 030

Class II Recalls (cont.)

ConMed Corporation Frazier and Poole Suction Instruments Various Product Codes and lot numbers (ARTG No: 115596)

(Reference: RN-2008-0495)

Date: 8/07/2008

Reason: During manufacture, the procedure for the inspection for sterile barrier integrity was not validated.

Further information: Medtel Pty Ltd, Mr Lorrence Platania - 0417 485 925

Identification of Affected Devices:

PRODUCT CODE	DESCRIPTION
33080	FRAZIER INSTR, 8 FRENCH, 50/C
33100	FRAZIER INSTR, 10 FRENCH, 50/C
33120	FRAZIER INSTR, 12 FRENCH, 50/C
33180	FRAZIER INSTR, 18 FRENCH, 50/C
35040	POOLE SUCTION INSTRUMENT 50/C

For ALL Catalog Numbers Listed above:

Devices that have packaging which exhibits the following lot code information:

Any of the above devices having a lot code that begins with the letters: **UR**

Any of the above devices having a lot code that begins with the letter: **E**

Any of the above devices having a lot code that ends with the number: **3**

Additionally, the **lot codes** for Frazier Instrument 10 French listed below are also affected:

Product Code	Lot Code
33100	0706191
	0706211
	0706221
	0706251
	0706261

Sterile and Non-sterile Jumbo Swabs and Sterile Mouth Toilet Pack (ARTG No: As noted)

(Reference: RN-2008-0494)

Date: 8/07/2008

Reason: The cotton bud may come off the stem of the swab.

Further information: Multigate Medical Products Pty Ltd, 02 9892 3400 - Jwana Majano



Class II Recalls (cont.)

<u>Re-order number</u>	<u>Product</u>	<u>Batches</u>	<u>ARTG No.</u>
21-888	Sterile Jumbo Swabs	21058 & 21068	AUST L 28728
22-555	Non-sterile Jumbo Swabs	20080109	ARTG # 125045
07-128	Sterile Mouth Toilet Pack	381028	AUST L 73075

Scorpio Series 7000 Tibial Baseplate Impactor/Extractor (3770-0000)

Cat # 3770-0000,

All batches

(ARTG No: 112787)

(Reference: RN-2008-0487)

Date: 8/07/2008

Reason: The impactor/extractor has the potential to fail to release from a tibial baseplate during use.

Further information: Stryker Australia Pty Ltd, Mr Lachlan McKenzie 1800 803 601

Allura Xper FD10 & FD 10/10 X-Ray Systems

(ARTG No. 98560

(Reference: RN-2008-0490)

Date: 9/07/2008

Reason: Philip's in-house testing has shown there to be a potential for the geometry software to intermittently crash when performing Digital Rotational Angiography (DRA) procedures.

Philips Axis and Irix Gamma Cameras

(ARTG: 117642)

(Reference: RN-2008-0503)

Date: 10/7/2008

Reason: Certain systems using Rotate Motion Shunt Resistors may over heat, resulting in the appearance of smoke, a burning smell and an E-Stop condition, which will disable the system rotate motion and other motions.

Further information: Philips Electronics Australia Ltd, 1800 251 400

Infinia Gamma Camera, Infinia Hawkeye, Infinia Hawkeye 4

(ARTG No: 96485)

(Reference: RN-2008-0487)

Date: 15/07/2008

Reason: Automatic Pressure Sensitive Device (PSD) may exhibit reduced sensitivity. Excessive pressure might be applied to patient's nose by the collimator pressure sensitive cover.

Further information: GE Healthcare Australia Pty Ltd, 1800 659 465 GE Customer Care Centre



Class II Recalls (cont.)

Savanah Raised Toilet Seat brackets purchased from May 2007 to May 2008 (ARTG No. 143757)

(Reference: RN-2008-0554)

Date: 29/7/2008

Reason: There is a manufacturing fault with the moulding of the rubber pad onto the bracket. A faulty seat may be less secure and the user may lose stability and fall

Further information: Pamela Caterson, surgical Synergies Pty Ltd, 1300 766 473

AA2112	Savanah Raised Toilet Seat 2" (50mm) without Lid
AA2112L	Savanah Raised Toilet Seat 2" (50mm) with Lid
AA2114Y	Savanah Raised Toilet Seat 4" (100mm) without Lid
AA2114L	Savanah Raised Toilet Seat 4" (100mm) with Lid
AA211401	Savanah Raised Toilet Seat Spare Brackets

T2 Reduction Spoon (Small Tip 28mm) Catalogue No. 18060125 All currently supplied lot numbers

(ARTG No. 114692)

(Reference: RN-2008-0558)

Date: 29/07/2008

Reason: The manufacturer has identified the potential for breakage of the reduction spoon. The potential hazard associated with breakage is elongation of surgery time (time under anaesthesia). Product used in orthopaedic procedures

Further information: Lachlan McKenzie, Stryker Australia Pty Ltd 1800 803 601