



August 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 August 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



## **SAFETY ALERT**

### **Welch Allyn AED10 and MRL Jumpstart Automatic Defibrillators**

**ARTG Number:** 99240

**REFERENCE:** RC-2009-RN-00560-3

**DATE AGREED:** 30/07/2009

**COMPANY:** Welch Allyn Australia Pty Limited

**PHONE:**

**REASON:** The directions for use of your Welch Allyn AED 10 or MRL JumpStart defibrillator contained in the user manual have been updated to improve the clarity of describing what should be done when the device displays a low battery status icon. (refer to letter).

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

## **CLASS I RECALL**

### **Sheribronch ET Tubes and Sheriswiv (used in thoracic surgery)**

**Catalogue Numbers:** 5-15401, 5-16028 to 5-16039 and 5-16128 to 16142

**ARTG Number:** 145889

**REFERENCE:** RC-2009-RN-00622-3

**DATE AGREED:** 7/08/2009

**COMPANY:** The Critical Group Pty Ltd

**PHONE:** 03 9544 5778 - David Carlin

**REASON:** The tether attached to the double swivel cap may partially or completely break at the attachment points. The broken tether may lodge inside the dual swivel tubing or body during shipment to the end user, resulting in the potential for accidental aspiration of the tether into the patient's lungs.

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

- The Queen Elizabeth Hospital

## CLASS II RECALL

### LCS® Duofix™ Femoral Component (used in orthopaedic surgery)

**REFERENCE:** RC-2009-RN-00584-3

**DATE AGREED:** 24/07/2009

**COMPANY:** Johnson & Johnson Medical Pty Ltd T/A Depuy Australia

**PHONE:** 03 9902 1348 - Susan Dafnias

**REASON:** Increased patient revision rates have been associated with the LCS® Duofix™ Femoral Component

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

- Whyalla Hospital

Product Code	Product Description
129407010	LCS Duofix FEM COMP HA SM RT
129407020	LCS Duofix FEM COM HA SM+ RT
129407030	LCS Duofix FEM COM HA MED RT
129407040	LCS Duofix FEM COM HA STD RT
129407050	LCS Duofix FEM COM HA STD+RT
129407060	LCS Duofix FEM COM HA LG RT
129407070	LCS Duofix FEM COM HA LG+ RT
129408010	LCS Duofix FEM COMP HA SM LT
129408020	LCS Duofix FEM COM HA SM+ LT
129408030	LCS Duofix FEM COM HA MED LT
129408040	LCS Duofix FEM COM HA STD LT
129408050	LCS Duofix FEM COM HA STD+LT
129408060	LCS Duofix FEM COM HA LG LT
129408070	LCS Duofix FEM COM HA LG+ LT

## CLASS II RECALL (Cont)

### Wiseguide Guide Catheter Impulse Angiographic (Diagnostic) Catheter and Expo Angiographic (Diagnostic) Catheter, Various lots/batches

**ARTG Number:** 137958  
**REFERENCE:** RC-2009-RN-00600-3  
**DATE AGREED:** 31/07/2009  
**COMPANY:** Boston Scientific Pty Ltd  
**PHONE:** 02 8063 8150 - Susana Diaz  
**REASON:** It has been determined that the sterile barrier packaging may be compromised. Gaps have been discovered between the side seals and the top seal approximately 3/8" in length.

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

- The Queen Elizabeth Hospital
- Lyell McEwin
- St Andrews

### ConMed Linvatec UltraPower Diamond Wheel Burs Expiry dates from July 2009 to April 2013 inclusive

REF 7021-092 25.4mm (Red),  
REF 7021-292 25.4mm (Mustard) M-51  
REF 7021-392 25.4mm (Lime) AM-51  
REF 7021-492 25.4mm TU-51

**ARTG Number** 126791  
**REFERENCE:** RC-2009-RN-00610-3  
**DATE AGREED:** 4/08/2009  
**SPONSOR:** ConMed Linvatec Australia Pty Ltd  
**PHONE:** 1800 238 238 Kevin Samuels  
**REASON:** The manufacturer has determined there is a possibility that the sterile packaging may have a breach in the sterile barrier. The sterility of the devices may be compromised.

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

- Whyalla
- TQEH
- RAH
- Calvary/Wakefield
- Sports Med



## CLASS II RECALL (Cont)

**ConMed Linvatec Lightwave Suction Ablator REF IA-2000-S**  
**Lot numbers 0407211, 0505061, 0505091, 0505161, 0505231, 0508121, 0602231, 0604241, 0606191. Expiry dates from July 2009 to September 2013 inclusive**

**ARTG Number:** 94017  
**REFERENCE:** RC-2009-RN-00613-3  
**DATE AGREED:** 4/08/2009  
**COMPANY:** ConMed Linvatec Australia Pty Ltd  
**PHONE:** 1800 238 238 Kevin Samuels  
**REASON:** The manufacturer has determined there is a possibility that the device may not shut off if the ablate button is released. This could cause possible risk of injury to user or patient.

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

- Ashford Hospital
- Calvary Hospital
- Calvary Wakefield Hospital
- Lyell McEwin Health Service
- Memorial Hospital
- Modbury Hospital
- North Eastern Community Hospital
- The Queen Elizabeth Hospital
- Royal Adelaide Hospital
- Whyally Hospital
- Sports Med SA
- Western Hospital

## CLASS III RECALL

**ADVIA Centaur Software Version 4.0 and ADVIA Centaur XP Software Version 6.0**

**REFERENCE:** RC-2009-RN-00659-3  
**DATE AGREED:** 28/08/2009  
**COMPANY:** Siemens Healthcare Diagnostics Pty Ltd  
**PHONE:** 1800 358 030 - Vince Chiera  
**REASON:** A series of software issues have been identified if users create customer-defined user ranges.

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

- SA Pathology
- Gribbles Pathology



Quality Assurance & Regulatory Affairs  
Unit 5/38-46 South Street  
Rydalmere, NSW 2116

**\*\*\* SAFETY ALERT\*\*\***  
**ARTG ID: 99240**  
**TGA Reference: RC-2009-RN-00560-3**

Dear Valued Customer:

We are writing to inform you that the directions for use of your Welch Allyn AED 10 or MRL JumpStart defibrillator contained in the user manual have been updated to improve the clarity of describing what should be done when the device displays a low battery status icon.

The primary update to the directions for use is addition of the following information regarding the low battery status.

- The flashing low battery status indicator means that the battery is beginning to weaken and should be replaced at the first opportunity. The AED 10 remains operable when the flashing low battery is activated, and it can be used on a patient in this condition or continued in use when connected to a patient if the low battery indicator activates. Replace the battery as soon as possible.
- If the AED 10 is subjected to cold temperatures near or outside of its low temperature operating limit of 32° F (0° C), the low battery status indicator may be triggered even with a new battery. The low battery indicator caused by cold temperature may cease when the device is warmed. Discharging the device to defibrillate a patient may cause sufficient warming to eliminate the low battery indicator or cause it to be intermittent.

Enclosed with this letter is a disc that contains the updated user manual for your device. Please discard the original user manual and replace it with this updated version.

The Therapeutic Goods Administration (TGA) has been advised of this Safety Alert.

We appreciate your cooperation in this matter.

Respectfully,



Grant Bennett  
QA/RA Manager  
Welch Allyn, Inc.