

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2015-RN-00803-1
Product Name/Description ⁱⁱⁱ	Medi-Trace Cadence Adult Multi-Function Defibrillation Electrodes, Pre-connect (used in conjunction with Automatic External Defibrillators) Medi-Trace Cadence Adult Multi-Function Defibrillation Electrodes Item Numbers: 22550PC, 22770PC Lot Numbers: 517521X, 519835X, 516313X, 519124X, 513426X ARTG Number: 186124
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class I
Recall Action Commencement Date ^{vi}	31/08/2015
Responsible Entity ^{vii}	Covidien Pty Ltd
Reason / Issue ^{viii}	This recall is being conducted due to a low-level potential for damage to the wire insulation which was identified during a review of our manufacturing process. No complaints for this issue have been reported from customers. The use of products with this condition may result in a potentially increased risk for either reduced or no patient therapy, arcing of current, sparking, and potential burns to the patient and/or clinician. No patient injuries have been reported regarding this damaged wire insulation issue.
Recall Action ^{ix}	Recall
Recall Action Instructions ^x	Users are asked to immediately quarantine and discontinue use of the affected devices and to arrange return as per the instructions supplied.
Contact Information ^{xi}	02 9429 3184 - Covidien

Footnotes

ⁱ Type of Product: Medicine, Medical Device, or Biological

ⁱⁱ TGA Recall Reference: Unique number given by the TGA

ⁱⁱⁱ Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

^{iv} Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.