

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2015-RN-01070-1
Product Name/Description ⁱⁱⁱ	Vented Paclitaxel Set (infusion set used during the administration of medication of anaesthetic drugs) Product Code: MMC9627S Lot Number: 14H13V434 ARTG Number: 108526
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	3/11/2015
Responsible Entity ^{vii}	Baxter Healthcare Pty Ltd
Reason / Issue ^{viii}	Baxter Healthcare has received reports of leaks at the spike's air vent subassembly. A leak in a Paclitaxel set may result in a breach in sterility of the fluid path with subsequent contamination of the solution. If not detected during priming or initial set up, this may lead to serious adverse health consequences. This leak may also result in potential skin contact which would result in potential skin irritation.
Recall Action ^{ix}	Recall
Recall Action Instructions ^x	Baxter Healthcare is advising users to inspect and quarantine any affected stock for return to Baxter.
Contact Information ^{xi}	1300 789 646 - Baxter Healthcare Customer Service

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.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue