Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-00033-1
Product Name/Description[iii]	Vented Spike with Clearlink (fluid transfer set) Product Code: EMC3481 All lot numbers affected ARTG Number: 149588
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	23/01/2014
Responsible Entity[vii]	Baxter Healthcare Pty Ltd
Reason / Issue[viii]	Baxter has determined that the Vented Spike with Clearlink, product code EMC3481 does not have sufficient stability data to support its labelling claims. As such, the sterile barrier cannot be assured for the duration of the claimed shelf life. Deterioration in the integrity of the device packaging has the potential to result in a breach of the sterile barrier which could lead to complications due to infection.
Recall Action[ix]	Recall
Recall Action Instructions[x]	Baxter is requesting users to locate and quarantine affected product. Affected product can be returned to Baxter for credit. Baxter has no alternative products to propose at this stage.
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