Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2015-RN-00774-1
Product Name/Description[iii]	Actifuse ABX and Actifuse MIS System Product Codes: 506005078047 Actifuse ABX, 1-2 mm, 2.5 mL 506005078048 Actifuse ABX, 1-2 mm, 5.0 mL 506005078049 Actifuse ABX, 1-2 mm, 10.0 mL 506005078057 Actifuse ABX, 1-2 mm, 20.0 mL, 506005078059 Actifuse ABX, 1-2 mm, 1.5 mL 506005078069 Actifuse MIS System, 1-2 mm, 7.5 mL 506005078071 Actifuse MIS System Refill, 1-2 mm, 7.5 mL Lot Numbers: ALL ARTG Numbers: 188736 & 193684
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	25/08/2015
Responsible Entity[vii]	Baxter Healthcare Pty Ltd
Reason / Issue[viii]	Baxter Healthcare is issuing a recall of Actifuse ABX and Actifuse MIS System products with expiry before 29 July 2017 due to the possibility that the products may have endotoxin levels above specification criteria. In surgical procedures where there is device contact with the cerebrospinal fluid through a dural opening (iatrogenic injury), the use of a medical device with increased endotoxin levels may augment the typical inflammatory reaction to surgery and contribute to adverse health consequences. Baxter has not received product-related adverse event reports that can be linked to cerebrospinal fluid exposure to increased levels of endotoxins.
Recall Action[ix]	Recall
Recall Action Instructions[x]	Users are asked to inspect their stock and to remove affected product from their facility and to contact Baxter Customer service to arrange replacements.
Contact Information[xi]	1300 789 646 - Customer Service

Footnotes

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