Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2016-RN-00142-1
Product Name/Description[iii]	DVR ePAKs All lots are affected Multiple Part Numbers affected ARTG Number: 210295
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	8/02/2016
Responsible Entity[vii]	Biomet Australia Pty Ltd
Reason / Issue[viii]	Iron oxidation has been found on components (mainly drill bits) contained in the DVR ePAKs. A delay in surgery, less than 30 minutes may occur if surgical staff proceeds to re-sterilise the product or locate alternative products. If oxidative material would flake off a component contained within the ePAK and enter the surgical field/wound, an inflammatory reaction may occur. The inflammatory reaction may result in a foreign body reaction and/or metal hypersensitivity.
Recall Action[ix]	Recall
Recall Action Instructions[x]	Zimmer Biomet is advising users to quarantine affected stock for return to Zimmer.
Contact Information[xi]	02 9483 5426 - Zimmer Biomet

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 banks and laboratories as well as wholesale as appropriate.