Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2015-RN-00972-1
Product Name/Description[iii]	Exeter Small and Large Tapered Pin Reamer (used as part of the Exeter Procedure Pack) Catalogue Numbers: 0932-0-000 (small) and 0932-2-000 (large) Lot Numbers (small): GW281208, GW284192, GW288907, GW282586, GW282310, GW298838, GX303720, GX302994 and GX301732 Lot Numbers (large): GW288908, GW282454 and GW288485 ARTG Number: 140892
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	1/10/2015
Responsible Entity[vii]	Stryker Australia Pty Ltd
Reason / Issue[viii]	Stryker has received a customer complaint which reported that during a total hip replacement the surgeon was using the Exeter small tapered pin reamer when the device fractured approximately 3 inches from the tip. This may result in the tip of the reamer detaching from the instrument. Should this occur and the fragment remain insitu, there are additional potential hazards including excessive metal ions and displacement from MRI.
Recall Action[ix]	Recall
Recall Action Instructions[x]	Stryker is advising users to quarantine any affected stock for replacement.
Contact Information[xi]	1800 803 601 - Stryker Australia

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.