

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2014-RN-01271-1
Product Name/Description ⁱⁱⁱ	Trilogy Bone Screws – 6.5mm X 35mm & 6.5mm X 25mm Lot numbers: 62748089, 62793494, 62793501, 62813612 & 62825611 ARTG number: 95692
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	5/12/2014
Responsible Entity ^{vii}	Zimmer Pty Ltd
Reason / Issue ^{viii}	Zimmer is initiating a recall of 1 lot of 25mm and 4 lots of 35mm length Trilogy bone screws due to fracture during insertion. Analysis of returned complaint devices, product in inventory, and device manufacturing records has identified tool marks isolated to one specific machining mill to be the cause of the fractures.
Recall Action ^{ix}	Hazard Alert
Recall Action Instructions ^x	Zimmer is notifying surgeons of the risks posed to patients implanted with the potentially affected bone screws. Additionally, hospitals are requested to quarantine any of the affected units in their possession. Zimmer will arrange for the return of affected product. Further information can be found on the TGA website at - http://www.tga.gov.au/alert/trilogy-bone-screws
Contact Information ^{xi}	02 9483 5400 - Zimmer

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