

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2014-RN-00733-1
Product Name/Description ⁱⁱⁱ	AVS ARIA Implant Inserter Item number: 48758500 (Located in Instrument Tray 48759040-T) Lots numbers affected: 107400, 10G906, 110214 ARTG number: 178870
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class I
Recall Action Commencement Date ^{vi}	18/07/2014
Responsible Entity ^{vii}	Stryker Australia Pty Ltd
Reason / Issue ^{viii}	Stryker has received reports of fracture of the vertebral PEEK spacers when implanted with the AVS ARIA Implant Inserter. According to the reported complaints, the proximal end of the implant either cracks or the tip breaks off in one fragment. There have been no reports of the broken fragment remaining in the surgical site.
Recall Action ^{ix}	Recall
Recall Action Instructions ^x	Stryker is advising their customers to quarantine any affected lots and will arrange for the return of any affected lots from the field.
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.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale