

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2013-RN-01151-1
Product Name/Description ⁱⁱⁱ	Teflon Tube T2 Humerus, Sterile (Intended to support the exchange of the Ball Tip Guide Wires for Smooth Tip Guide Wires for nail insertion) Catalogue Number: 18060073S Lot Number: K0432D3 ARTG Number: 139623
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	8/11/2013
Responsible Entity ^{vii}	Stryker Australia Pty Ltd
Reason / Issue ^{viii}	Stryker has become aware that certain lots of the Teflon Tube have demonstrated a deficient seam in the sterile packaging. There is the potential for the inner pouch to be unsterile due to missing seal integrity.
Recall Action ^{ix}	Recall
Recall Action Instructions ^x	Stryker is requesting hospitals to inspect their stock to determine if they have units from the affected lots. All affected product is to be returned to Stryker.
Contact Information ^{xi}	1800 803 601 - Stryker Regulatory Affairs/Quality Assurance

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