

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2014-RN-01325-1
Product Name/Description ⁱⁱⁱ	Sensei X Robotic Catheter System Model Numbers: 02057 and 08257 ARTG Number: 157314
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class I
Recall Action Commencement Date ^{vi}	19/12/2014
Responsible Entity ^{vii}	St Jude Medical Australia Pty Ltd
Reason / Issue ^{viii}	There is a potential for the Set-Up Joint Sub-assembly to become loose relative to the operating table. Should this issue occur during clinical use, it may potentially result in uncontrolled catheter motion. Uncontrolled catheter motion could result in cardiac tamponade or perforation of the heart.
Recall Action ^{ix}	Recall for Product Correction
Recall Action Instructions ^x	The Customer is requested to ensure that the RCM is secure and tightly connected to the patient table before starting a procedure and check that all clamps are properly tightened. In addition, ensure that the RCM does not come into contact with other laboratory equipment, as this may produce forces capable of dislodging the RCM. In the event the clamp is found to be loose, customers are advised not use the system and to contact St.Jude Medical immediately.
Contact Information ^{xi}	02 9936 1200 - St Jude Medical Australia Pty Ltd

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