Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2013-RN-01086-1
Product Name/Description[iii]	ATTAIN HYBRID Guide Wires (used to aid the placement of Medtronic transvenous left ventricular leads in the coronary vasculature) Model GWR419688 Batch Numbers: 0006840866, 0006840879, 0006873688 ARTG Number: 153354
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	22/10/2013
Responsible Entity[vii]	Medtronic Australasia Pty Ltd
Reason / Issue[viii]	Medtronic has identified the potential for an issue with a specific subset of batch numbers of the Guide Wires where the PTFE (polytetrafluoroethylene) coating could delaminate and detach from the Guide Wire. This issue affects a subset of a range of Guide Wires manufactured from mid-April 2013. Delamination and detachment of the PTFE coating may lead to embolic occlusion and thrombosis in coronary, cerebral, peripheral or pulmonary vasculature. Vascular thrombosis and/or occlusion have the potential to result in irreversible damage or injury to vital organs including myocardial infarction or stroke.
Recall Action[ix]	Recall
Recall Action Instructions[x]	Customers are asked to quarantine all unused product for returning it to Medtronic. For affected products that have been used, Medtronic is advising that patients should continue to be managed in accordance with hospitals standard patient management protocol.
Contact Information[xi]	1800 668 670 - Medtronic Australasia

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 /