Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-00531-1
Product Name/Description[iii]	Axium Neurostimulator Leads (MN20450-50AU, MN20450-90AU) KIT IMPLANT LEAD 50CM Model MN20450-50AU KIT IMPLANT LEAD 90CM Model MN20450-90AU ARTG number: 202325
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	23/05/2014
Responsible Entity[vii]	Spinal Modulation Pty Ltd
Reason / Issue[viii]	Over 2000 DRG leads have been implanted in patients worldwide. At this time, there have been 10 reports of lead breakage during attempted lead removal, resulting in lead fragments remaining implanted in the patient. To date, there have not been any reported complications or long-term sequelae surrounding these events. During lead removal of a permanently implanted lead, the Spinal Modulation implant instructions and warnings must be followed to help prevent lead breakage.
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	Spinal Modulation is undertaking this action to provide additional information and clarify the steps necessary to ensure safe lead removal after permanent implantation. Some of these methods are described in the "Physician Implant Manual". Additional information identified in the letter will be included in the "Physician Implant Manual" for the future release of the product.
Contact Information[xi]	03 9225 5265 - Spinal Modulation

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