Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2015-RN-00925-1
Product Name/Description[iii]	Medtronic Navigated Solera Driver Tips for Spinal Surgery Model numbers: 9735023, 9735024, 9735025, 9735026, 9735027, 9734856, 9734857, 9734279, 9734373 Instrument set or kit models numbers (which contains the drivers) - 9735283, 9735283-G02, 9734632, 9734647, 9734648, 9735281, 9735278, 9735282, 9735279, 9735280 All serial numbers ARTG Numbers: 119952 and 120114
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	18/09/2015
Responsible Entity[vii]	Medtronic Australasia Pty Ltd
Reason / Issue[viii]	Complaints have been received by Medtronic related to broken, bent or damaged screwdriver tips. Under certain use conditions, the torque required to fully seat a pedicle screw may be higher than the screwdriver tip can withstand. Those conditions include: • The hole for the screw not drilled to the proper diameter • The hole for the screw not tapped adequately, either in the diameter or the length • Dense bone • Large diameter screws The screwdriver tip breaking could result in the extension of the surgery due to the need to find a replacement screwdriver, and if broken, extract the broken tip from the screw to complete the insertion, or the removal of the tip from the patient.
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	Medtronic is modifying the instructions for use (IFU) for the navigated screwdrivers to add additional warnings related to the careful inspection of the instruments regularly for damage and the importance of knowledge of the operating procedures, patient selection, and product information. The revised IFUs will be included with all new navigated screwdrivers. Some images of conditions to look for during inspection is included in the customer letter. Revised IFUs will be also provided with the customer letter.
Contact Information[xi]	02 9857 9179 - Medtronic