Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-00905-1
Product Name/Description[iii]	St. Jude Medical Ellipse VR/DR Implantable Cardioverter Defibrillators (ICDs) Models: CD1277 (-36 and -36Q) , CD1377 (-36, -36Q, -36C and -36QC), CD2277 (-36 and -36Q), CD2377 (-36, -36Q, -36C and -36QC) Serial Numbers: beginning with "1" that are below 1132470, beginning with the number "7" that are below 7126267 and all serial numbers beginning with an "8" are affected. ARTG Numbers: 207181, 207182, 207183, 207184, 207185, 207186, 207187, 207189, 202934, 202938, 198821, 198822
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	18/08/2014
Responsible Entity[vii]	St Jude Medical Australia Pty Ltd
Reason / Issue[viii]	St. Jude Medical (SJM) has received complaints that extended charge time may present as a result of internal damage to the capacitors used in the high voltage charging circuitry of the subject devices. As designed, the device will deliver the available energy on the capacitors once the charge time limit of 32 seconds is reached, even if the energy is less than the programmed value. This anomaly may occur during capacitor maintenance or charging for high voltage therapy, and may result in delayed delivery of high voltage therapy and/or delivery of part of a programmed high voltage therapy shock. There have been no reported cases of an Ellipse device failing to deliver high voltage therapy to a patient when needed.
Recall Action[ix]	Hazard Alert
Recall Action Instructions[x]	St. Jude Medical is providing appropriate patient management recommendations to surgeons for managing patients who are implanted with affected devices. Device replacement is not recommended for an Ellipse device exhibiting normal charge times, and patients should continue to be followed at routine follow-up intervals. Surgeons are advised not to use any Ellipse devices which may be on their shelves. St. Jude Medical is advising customers that the affected stock will be retrieved and replaced by new Ellipse ICDs with the redesigned high voltage capacitor eliminating the source of capacitor damage at the front alignment hole. For more details, please see http://www.tga.gov.au/safety/alerts-device-ellipse-cardioverter-defibrillators-140820.htm .
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