



The Cardiac Society
of Australia and
New Zealand

Level 6 Suite 601
1 Castlereagh Street
Sydney NSW 2000
Ph 61 2 9226 7900
E info@csanz.edu.au
www.csanz.edu.au
ABN 23 003 635 505

ANZCDACC Advisory Notice 12th November 2015

Device: St Jude Optisure Dual Coil Defibrillation Leads

Models: LDA220Q/52, LDA220Q/58, LDA220Q/65 and LDP 220Q/58

Advisory Grade TGA: TBA however likely Class I

ANZDACC Advisory Grade: Semi-urgent

Number in Australia: 19 implanted in Australia. Zero in New Zealand

Risk: There is the potential for lead damage to result in loss of defibrillation therapy during attempted shock delivery when programmed to the RV to SVC and can high voltage therapy configuration.

Description: During the manufacturing process of a limited number of St Jude Optisure Dual Coil Defibrillation leads, a trim technique to remove excess medical adhesive around the SVC shock coil may have introduced damage to the lead's insulation.

Presentation: No patients have been harmed to date. All Australian patients have Dynamic Tx and Home monitoring which will potentially protect patients who are at risk by detecting sensing issues and managing defibrillation issues.

Advice: For patients implanted with a potentially-impacted St Jude Optisure lead connected to a device with DynamicTx (all cases in Australia) the technology must be programmed "On", if a short circuit is detected the device will automatically change the shock configuration by vector switch to enable high voltage delivery. Enroll patients in home monitoring (all enrolled in Australia). Otherwise observe as normal.

We have been informed by the company (St Jude Medical) that all Australian affected leads have Dynamic Tx and Home monitoring. If you know of any patients in whom this is not true, please contact ANZCDACC via details on CSANZ website and your St Jude Medical representative immediately for alternative advice.