APHRS Advisory Notice 12th November 2015 Device:

St Jude Optisure Dual Coil Defibrillation Leads

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

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.

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. Otherwise observe as normal.