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General Surgery-ICD

St. Jude Medical makes no specific medical recommendations regarding treatment of patients implanted with St. Jude Medical/Ventritex implantable cardioverter defibrillators (ICDs). However, because the typical patient is likely to encounter a variety of situations capable of interfering with proper function of his/her device, we are providing a general guide to patient limitations and therapies involving surgery.

During certain types of surgery the implanted ICD may be exposed to strong electromagnetic (EMI) fields. These fields may cause operational problems in the pulse generator that include, but are not limited to: cessation of or intermittent bradycardia pacing and inadvertent anti-tachycardia pacing, cardioversion, or defibrillation. Additionally, high-energy induced or conducted currents are capable of resetting the programmed parameters and damaging the pulse generator and tissue surrounding the implanted lead electrodes.

The ICD may detect the electric impulses from electrosurgery as "electrical noise," which could mask the underlying rhythm of the heart and cause a noise reversion. During a noise reversion, the device will not deliver therapy (therapy includes ATP pacing, cardioversion and defibrillation) and will revert to the programmed Noise Reversion Mode, which is programmable to Pacer Off or an asynchronous pacing mode. More importantly, the device may misinterpret these electric impulses as cardiac events, resulting in inappropriate arrhythmia detection and therapy delivery. A high voltage shock delivered to a patient during a procedure may disrupt delicate surgery. To avoid inappropriate therapies, St. Jude Medical recommends the following:

- Place a magnet over the device, positioned off-center, to suspend arrhythmia detection. If the device is exposed to a constant magnetic field of sufficient strength, a magnet reversion is triggered which disables arrhythmia detection. Once the magnetic field is removed, arrhythmia detection is again possible. A magnet reversion will not affect the bradycardia pacing function of the device; therefore, the need for asynchronous pacing must be evaluated.

OR

- Program the device to a non-tachyarrhythmia configuration, *e.g.* "Defib Off," "All Functions Off" or "Brady Pacing Only."

Magnet placement is for temporary inhibition of tachyarrhythmia therapy. If inhibition is required for longer than eight hours, program the device to a non-tachyarrhythmia configuration. While tachyarrhythmia therapies are disabled, it is advised to monitor the patient and have external defibrillation available.

Please contact Tachycardia Technical Services at 1-800-722-3774 if you have any additional questions or concerns.