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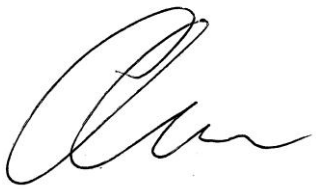
29 January 2014

Dear Colleague,

As part of St. Jude Medical's commitment to communications on device performance, and in consultation with our Medical Advisory Board, we are providing to you information regarding possible effects of electrocautery on older generation St. Jude Medical pacemakers. Please see the attached document for specific details.

As always, please feel free to contact me, your St. Jude Medical representative, or any member of the St. Jude Medical team with any additional questions or concerns.



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Considerations When Using Electrocautery in Patients Implanted with Older Generation St. Jude Medical Pacemakers

(Affinity, Entity, Integrity, Identity, Sustain, Frontier, Victory and Zephyr models)

St. Jude Medical has reviewed incident reports on specific older generation pacemaker models exposed to electrocautery. When devices from these pacemaker families are exposed to electrocautery (as well as the PEAK PlasmaBlade™blade), they may exhibit a temporary change in function that could persist for 30 seconds or longer after the electrocautery exposure has been terminated. The duration of the effect depends on several factors including the battery voltage of the device, the energy of the electrocautery output, and the distance from the electrocautery source to the implanted system. The most clinically significant observation has been loss of capture due to a transient reduction in the pacing output voltage. Placing a magnet over the device or programming to an asynchronous pacing mode will not prevent this temporary reduction in pacing output.

The effects of electrocautery on cardiac implantable electronic device operation are well documented in the scientific literature and most, if not all, pacemaker and implantable cardioverter defibrillator (ICD) User's Manuals include labeling about the use of electrosurgery equipment and its possible effects on the operational characteristics and/or internal circuitry of these devices.

As is the case with all perioperative assessments in patients with cardiac implantable electronic devices, evaluating the individual patient's dependence on the implanted device should be assessed prior to any procedure that would ordinarily require electrocautery, particularly a pacemaker procedure. If pacemaker dependency is identified, either do not use electrocautery or employ appropriate precautions to ensure that the heart rate will be supported in the presence of electrocautery. Consideration of placing a temporary transvenous pacemaker is appropriate. [1,2]

All St. Jude Medical pacemaker and ICD User's Manuals provide Warnings and Precautions regarding the use of electrosurgical devices in the vicinity of an implanted device.

Importantly, the more recent families of St. Jude Medical pacemakers (Accent and Anthem) and all ICDs are not subject to this temporary change in function from the extended effects of electrocautery.

If you have any questions, regarding the information provided, please contact your St. Jude Medical Representative or Technical Services at 800-722-3774.

References:

1) Hayes and Friedman, Cardiac Pacing, Defibrillation and Resynchronization, 2nd Edition, p. 192
2) Ellenbogen and Wood, Cardiac Pacing and ICDs, 4th Edition, p. 227