Effects of Electrosurgery on St. Jude Medical Implantable Cardiac Pacemakers

Background
The use of electrosurgery can affect the operation of cardiac pacemakers. While all St. Jude Medical pacemakers incorporate circuits and designs intended to prevent or minimize such effects, the high energy levels used in electrosurgery can temporarily interfere with device operation or cause permanent damage. The most likely effects arise from the device sensing electromagnetic interference (EMI) generated by the electrosurgery system; however, circuit damage and a direct coupling of radiofrequency energy to cardiac muscle are also possible.

Potential Effects
A summary of potential effects is provided in the table below and is based on device testing at St. Jude Medical, clinical experience and a review of the scientific literature.

<table>
<thead>
<tr>
<th>Potential Effect</th>
<th>Estimated Frequency</th>
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<tbody>
<tr>
<td>Temporary inhibition of pacing</td>
<td>Common</td>
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<tr>
<td>Reversion to asynchronous pacing</td>
<td>Common</td>
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<tr>
<td>Temporary loss of capture (Affinity to Zephyr)</td>
<td>Common</td>
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<tr>
<td>Temporary loss of capture (Accent and newer, Microny and Regency)</td>
<td>Uncommon</td>
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<td>Pacing at elevated or erratic rates</td>
<td>Uncommon</td>
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<td>Backup VVI pacing</td>
<td>Uncommon</td>
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<tr>
<td>Induction of arrhythmias or fibrillation</td>
<td>Rare</td>
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<tr>
<td>Circuit damage leading to erratic function or loss of pacing</td>
<td>Rare</td>
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<tr>
<td>Tissue damage at lead-tissue interface, leading to loss of sensing and/or elevated pacing thresholds</td>
<td>Rare</td>
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St. Jude Medical has reviewed incident reports on specific older generation pacemaker models (Affinity, Entity, Integrity, Identity, Verity, Sustain, Frontier, Victory, and Zephyr models) exposed to electrosurgery. When devices from these pacemaker families are exposed to electrosurgery (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 electrosurgery exposure has been terminated. The duration of the effect depends on several factors including the battery voltage of the device, the energy of the electrosurgery output, and the distance from the electrosurgery 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.
Recommendations
Per the 2011 HRS perioperative consensus committee, an approach that limits electrosurgery usage to short bursts (4 to 5 seconds or less) may be a safer approach than either reprogramming or placement of a magnet over the pulse generator\(^1\). If extended electrosurgery is necessary, placing a magnet over the device or reprogramming to an asynchronous mode may be necessary to prevent oversensing. If electrosurgery is necessary, the following recommendations will help minimize the potential for complications.

Prior to the procedure
- If electrosurgery will be used in the vicinity of the pacemaker, loss of capture may occur due to threshold changes at the tip-tissue interface, or as a result of reduced pacing output amplitudes in older Affinity to Zephyr devices. To minimize the likelihood of loss of capture, the output can be programmed to a higher output prior to electrosurgery.
- If the patient is pacemaker dependent or extended electrosurgery is necessary, placing a magnet over the device or reprogramming to an asynchronous mode may be necessary to prevent oversensing and inhibition of pacing. In patients with older Affinity to Zephyr devices, clinicians may wish to consider placement of a temporary transvenous pacemaker.

During the procedure
- Monitor the patient’s pulse and/or ECG during electrosurgery.
- Keep the electrosurgical tip more than 15 cm (6 inches) away from the implanted device and pacing lead(s).
- Use short-duration, intermittent and irregular bursts at the lowest feasible energy levels.
- Position the electrosurgery system’s ground plate so that the current pathway does not pass through or near the pacemaker and lead(s).
- Where possible, use a bipolar electrosurgery system.
- Have temporary pacing and defibrillation equipment available.

After the procedure
- A thorough pacing system evaluation by the patient’s following physician should be considered, especially in dependent patients or if a change in pacing performance is suspected.
- If the device was programmed to an asynchronous pacing mode or to higher outputs, reprogram the device to the desired settings.

If you have any questions on this topic, please contact St. Jude Medical Technical Services:

- Technical Services (U.S.)
  Phone Number  800.722.3774
  Email technicalservices@sjm.com

- Technical Services (International)
  Phone Number  +46.8.474.4147
  Email technical.support@sjm.com