Effects of Muscle Stimulators on St. Jude Medical Implantable Cardiac Rhythm Devices

Background
Muscle stimulators elicit the contraction of muscles using electric impulses. Muscle stimulators are used as a testing tool for evaluating muscular function as well as a rehabilitation and preventive tool.

Potential Effects
The electrical signals from the muscle stimulator can interfere with the normal operation of pacemakers and implantable cardioverter defibrillators (ICDs). If the muscle stimulator does interfere with the pacemaker, either inhibition or reversion to asynchronous pacing may occur. Bipolar pacemakers are much less likely to be affected by interference than are unipolar pacemakers.

The electrical impulses from the muscle stimulator may be interpreted as “electrical noise” in ICDs and cause a noise reversion. During a noise reversion the device will not deliver therapy (therapy includes ATP pacing, cardioversion, and defibrillation). If muscle stimulator impulses are misinterpreted as cardiac events in an ICD, inhibition of bradycardia pacing and/or inappropriate arrhythmia detection and therapy delivery are possible. Extraneous signals from the muscle stimulator will not cause any damage to the pacemaker or ICD.

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

<table>
<thead>
<tr>
<th>Potential Effect</th>
<th>Estimated Frequency</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Pacemakers</td>
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<tr>
<td>Inhibition of pacing</td>
<td>Uncommon</td>
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<tr>
<td>Asynchronous pacing/noise reversion</td>
<td>Uncommon</td>
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<tr>
<td>Inappropriate therapy delivery</td>
<td>Not applicable</td>
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Recommendations for In-Office Use

Before the procedure
• Program the sensing polarity to bipolar in pacemakers.
• Reprogramming to an asynchronous mode (pacemakers and ICDs) and/or disabling high voltage therapy (ICDs) may be necessary.

For ICDs the tachycardia detection and response features can be deactivated by:
• Placing a magnet over the device. This suspends tachyarrhythmia detection and response as long as the magnet is held in place over the device and the magnet response feature has not been disabled.
• Although generally not necessary, high voltage therapies may be indefinitely suspended via temporarily programming to “Tachy Therapy is Disabled” or “Tachy Zones Off” depending
on the programmer options for each specific model. When anti-tachyarrhythmia therapies are disabled, monitor the patient and ensure that external defibrillation capabilities are available.

**During the procedure**
- If therapies were disabled or a magnet was placed over the ICD, monitor the patient’s pulse and/or ECG during muscle stimulation.

**After the procedure**
- If a magnet was placed over the ICD, normal programmed function resumes once the magnet is removed and the ICD does not require interrogation to validate reactivation.
- If the device was programmed to an asynchronous pacing mode or Tachy Therapy Disabled/Off, reprogram the device back to the desired settings.

**Recommendations for At-Home Use**
- The clinician may want to consider evaluating operation of the implanted device while using the muscle stimulator at maximum outputs.

If you have any questions on this topic, please contact St. Jude Medical Technical Services at 800-722-3774.