Effects of Bone Growth Stimulation on St. Jude Medical Implantable Cardiac Rhythm Devices

Background
A bone growth stimulator is a machine that uses either electronic stimulation or ultrasound to heal broken bones. A bone growth stimulator is only used when a bone does not heal for a very long period of time--usually it is given a minimum period of nine months to heal naturally.

Potential Effects
Based on information from two manufacturers (Biolectron Spinalpak and Orthopak) we would not anticipate any damage or reprogramming of the pacemaker or implantable cardioverter defibrillator (ICD) due to bone growth stimulation. Ultrasonic stimulators are less likely to interfere with device function than electronic stimulators. We have also received verbal reports that bone growth stimulation therapy has been performed on pacemaker and ICD patients uneventfully.

It is possible that EMI from the bone growth stimulator could be picked up by the telemetry wand during device interrogation but does not affect device function.

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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pacemakers</td>
</tr>
<tr>
<td>Oversensing</td>
<td>Rare</td>
</tr>
</tbody>
</table>

Recommendations
The clinician may wish to verify appropriate device function during the first use of the bone growth stimulator. Although we don’t anticipate any interaction, the clinician may elect to reprogram the device as necessary.

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