Effects of Extracorporeal Shock Wave Lithotripsy (ESWL) on St. Jude Medical Implantable Cardiac Rhythm Devices

Background
Shock wave lithotripsy is a medical procedure which uses a spark gap or electromagnetic transducer to produce a shock wave to break up calculi, for example in patients with kidney stones. The original lithotripter, the Dornier HM3, generates hydraulic shocks from an underwater spark gap while the patient lies in a water bath. Newer lithotripters use electromagnetic (Siemens Lithostar) or piezoelectric (Wolf Piezolith) shock wave generators instead of a water bath.

Potential Effects
The Dornier HM3 lithotripter (used in a non R-wave triggered mode) shock wave may cause an additional myocardial depolarization. In the non-triggered mode it also may cause single beat inhibition, but this is generally not noticed by the patient.

Additionally, the shock wave produced by the Dornier HM3 lithotripter has the potential to permanently damage the piezoelectric crystal in the activity sensor, silicon circuitry, and other hardware components of an ICD or pacemaker, particularly if the ESWL focal point is directed towards the device.

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 of Dornier HM3 System</th>
<th>Estimated Frequency Pacemakers</th>
<th>Estimated Frequency ICDs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single beat depolarization (in non-triggered mode)</td>
<td>Common</td>
<td>Common</td>
</tr>
<tr>
<td>Single beat inhibition</td>
<td>Uncommon</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Temporary increased sensor rate</td>
<td>Uncommon</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Reversion to magnet mode</td>
<td>Uncommon</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Inappropriate therapy delivery</td>
<td>Not applicable</td>
<td>Rare</td>
</tr>
<tr>
<td>Component damage</td>
<td>Rare</td>
<td>Rare</td>
</tr>
</tbody>
</table>

*Note: No potential interactions are expected or have been reported on newer systems such as Siemens Lithostar and Wolf Piezolith.

Recommendations

**Patient Management Before Therapy**

- **For newer systems such as Siemens Lithostar and Wolf Piezolith:** No precautions before therapy are necessary provided the patient has a pectoral implant.
- **For Dornier HM3 systems:**
  - Program the mode to VVI. Program the mode to VOO if the patient is pacemaker dependent. Programming to a single chamber mode of VVI/VOO prevents the lithotripter from inappropriately triggering off of an atrial pacing spike.
  - Disable tachycardia therapy on ICDs. This can be done by placing a magnet over the ICD.
• For all ESWL systems: There is a risk of damage for abdominally placed pacemakers and ICDs and therefore lithotripsy should be avoided in these patients.

Patient Management During Therapy
• Keep the lithotripter focal point at least 15 cm (6 inches) away from the pacemaker or ICD, especially in devices that utilize a piezoelectric crystal in the activity sensor.
• Using a triggered mode on the Dornier HM3 lithotripter will prevent inappropriate depolarization and potential arrhythmia induction. On newer electromagnetic or piezoelectric systems the triggered mode is not required.

Patient Evaluation following Completion of ESWL Therapy
• Following the completion of ESWL, reprogram the device back to the desired settings. If the activity sensor is responding inappropriately post-ESWL therapy, the function of the activity sensor should be assessed.

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