GUIDANT IMPLANTABLE PACEMAKERS


**Issue:** Potential loss of therapy due to hermetic seal degradation, resulting in a higher than normal moisture content within the pacemaker case late in the devices service life.

### Model Numbers Affected

<table>
<thead>
<tr>
<th>Device Family</th>
<th>Model Nos</th>
<th>Device Family</th>
<th>Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>DISCOVERY II</td>
<td>0481, 0981, 1184, 1186, 1187, 1283, 1284, 1285, 1286</td>
<td>PULSAR MAX</td>
<td>1170, 1171, 1270</td>
</tr>
<tr>
<td>DISCOVERY</td>
<td>1174, 1175, 1273, 1274, 1275</td>
<td>PULSAR MAX II</td>
<td>1180, 1181, 1280</td>
</tr>
<tr>
<td>PULSAR</td>
<td>0470, 0870, 0970, 0972, 1172, 1272</td>
<td>MERIDIAN</td>
<td>0476, 0976, 1176, 1276</td>
</tr>
<tr>
<td>*INTELSIS II</td>
<td>1483, 1484, 1485, 1384, 1385, 1349, 1499</td>
<td>CONTAK TR</td>
<td>1241</td>
</tr>
<tr>
<td>*VIRTUS Plus II</td>
<td>1380, 1480</td>
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</tr>
</tbody>
</table>

**Devices manufactured between:**


**Number of devices implanted in Australia (as identified by Guidant):**

Approximately 550 devices remain implanted. 1375 devices were implanted.

**Adverse effects:**

Premature battery depletion with resulting loss of telemetry and/or loss of pacing output without warning

Inappropriate accelerometer function (if programmed ON) resulting in:
- Sustained pacing at the Maximum sensor Rate (MSR)
- Lack of appropriate accelerator response during activity
- Appearance of reset warning message upon interrogation
- Inappropriate early display of replacement indicators

Adverse events are the same but at lower incident rate

Guidant’s projected rate of occurrence for reported events for the remaining lifetime of active devices

Initially estimated to be between 0.17% and 0.51%

Now estimated to be between 0.31% and 0.88%

**NSW DEPARTMENT OF HEALTH SUGGEST THE FOLLOWING ACTIONS:**

**That Directors of Clinical Operations:**

1. Ensure that the letter from Guidant has been received,
2. Consider the relevancy of this information to their Area, and if relevant,
3. Ensure appropriate Clinical Risk Management strategies are in place within your Area Health Service to manage the level of risk to patients.
GUIDANT IMPLANTABLE PACEMAKERS
A brief summary of action required by Guidant.

Affected Guidant Implantable Pacemakers:
PULSAR® MAX, PULSAR, DISCOVERY®, MERIDIAN®, PULSAR MAX 11, DISCOVERY 11, CONTAK® TR

Guidant implantable pacemakers manufactured between: 25 November 1997 & 26 October 2000

Guidant recommended actions:
Reassess patients in light of the increased projected rate of occurrence
- Consider replacing devices for pacemaker dependent patients.
- Advise patients of actions to take if they experience syncope or light-headedness or have new or increased symptoms of heart failure.
- Select a suitable MSR setting, given the rare possibility that inappropriate sustained pacing at MSR can occur, or
- Consider programming the accelerometer OFF to prevent inappropriate sustained pacing at MSR and potential consequences of sustained rapid heart rate.
- Consider increasing frequency of programmer follow-ups
- Consider increasing the frequency of transtelephonic monitoring to detect inappropriate sustained MSR pacing and or loss of pacing output.

Guidant implantable pacemakers manufactured between: 19 October 1998 & 5 December 2000

Guidant recommended actions:
Physician assessment of each patient taking into account those recommendations for the original alert population and the lower incidence rate.

Related Information:
For a copy of the letter please go to the following link:
http://www.guidant.com/physician_communications/