GUIDANT

URGENT MEDICAL DEVICE SAFETY INFORMATION & CORRECTIVE ACTION

July 18, 2005

Re: PULSAR® MAX, PULSAR, DISCOVERY®, MERIDIAN®, PULSAR MAX II, DISCOVERY II, VIRTUS PLUS® II, INTELIS II and CONTAK® TR devices

Dear Doctor,

This letter is intended to inform you of important safety information regarding a *subset* of PULSAR MAX, PULSAR, DISCOVERY, MERIDIAN, PULSAR MAX II, DISCOVERY II, VIRTUS PLUS II, INTELIS II and CONTAK TR pacemakers manufactured between November 25, 1997 and October 26, 2000. Our records indicate that you have implanted or are monitoring patients with these devices. This letter advises physicians and their patients about the potential unanticipated device behaviors and is intended to limit adverse events. The United States Food and Drug Administration (FDA) may classify this action as a recall.

Issue Description and Clinical Implications
Guidant's Cardiac Rhythm Management Quality System has recently determined that a hermetic sealing component utilized in these devices may experience a gradual degradation, resulting in a higher than normal moisture content within the pacemaker case late in the device's service life. This may lead to one or more of the following behaviors:

- Premature battery depletion resulting in loss of telemetry and/or loss of pacing output without warning
- Inappropriate accelerometer function (if programmed ON), resulting in
  - Sustained pacing at the programmed maximum sensor rate (MSR)
  - Lack of appropriate accelerometer rate response during activity
- Appearance of a reset warning message upon interrogation
- Inappropriate early display of replacement indicators

***Important Note**: While interrogation of the device may identify devices that have already experienced this failure mode, Guidant has not identified any test that will predict if a device will exhibit this failure mode in the future.*

***Important Note**: While inappropriate accelerometer function has been observed in 60% of the failures reported to date, it cannot be relied upon as an early indicator of this failure mode.*

***Important Note**: While disabling accelerometer function will mitigate inappropriate MSR pacing, moisture penetration can still cause the other behaviors described above, including loss of output.*

Engineering analysis has determined that these clinical behaviors may be exhibited individually or in combination. As of July 11, 2005, Guidant has identified sixty-nine (69) devices that may have exhibited this failure mode. Fifty-two (52) such failures have been confirmed worldwide; four (4) devices are currently undergoing analysis, and thirteen (13) devices may have experienced this failure mode but were not returned to Guidant for confirmation.

Of the 78,000 devices originally distributed, approximately 28,000 devices remain implanted worldwide; 18,000 of these devices remain in service in the United States with an average implant age of sixty-nine (69) months. No failures have been reported prior to forty-four (44) months of service, and the likelihood of occurrence increases with implant time. Guidant's modeling based on field experience and statistical life-table analysis predicts the rate of failure in the remaining active implanted devices to be between 0.17% and 0.51% over the remaining device lifetime. The actual occurrence rate and predicted rate may be greater than the stated numbers, because of underreporting and the limitations of projections.

The clinical behaviors associated with this failure mode can result in serious health complications. Guidant has confirmed twenty (20) reports of loss of pacing output associated with this failure mode, including five (5) patients experiencing syncope. Loss of pacing output has also been associated with reports of presyncope requiring hospitalization. Additionally, Guidant has received two reports of sustained MSR pacing in which heart failure may have developed in association with sustained high rate pacing. In one report, a patient whose device exhibited sustained MSR pacing was admitted to the hospital with multiple health issues and later expired. It is unknown if this device experienced the failure described above as the device was not returned and this failure mode could not be confirmed.

Recommendations

When determining the most appropriate patient management option, physicians should consider the unique needs of each individual patient, including pacemaker dependency, as well as the age and remaining service life of the pacemaker.

Guidant recommends the following:

- Consider replacing devices for pacemaker-dependent patients.
- Advise patients to seek attention immediately if they notice a prolonged rapid heart rate, experience syncope or lightheadedness, 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.
- Consider increasing the frequency of programmer follow-ups. This increases the likelihood of detecting a failure that has already occurred, but does not guarantee that the device will not exhibit this failure mode in the future. At each patient follow-up:
    - Evaluate for the clinical behaviors described above.
    - Evaluate battery status indicator ("gas gauge") for signs of early or rapid depletion between sequential follow-up visits.
    - Evaluate the accelerometer rate response (for devices with this feature).

Accelerometer Status	Evaluation Criteria
ON	• Look for inappropriate MSR pacing or pacing higher than the programmed lower rate limit while the patient is at rest. • Look for lack of rate response with activity (ie, isometrics, short hall walk).
OFF	*Temporarily* program the accelerometer ON and evaluate as described above.

- Consider increasing the frequency of transtelephonic monitoring to detect inappropriate sustained MSR pacing and/or loss of pacing output.

If any of these device behaviors are observed, contact your local Guidant representative or Guidant Technical Services for troubleshooting and recommendations.

Devices Impacted
A subset of the following model numbers are affected by this communication:

Device Family	Model Numbers
PULSAR MAX	1170, 1171, 1270
PULSAR	0470, 0870, 0970, 0972, 1172, 1272
DISCOVERY	1174, 1175, 1273, 1274, 1275
MERIDIAN	0476, 0976, 1176, 1276
PULSAR MAX II	1180, 1181, 1280
DISCOVERY II	0481, 0981, 1184, 1186, 1187, 1283, 1284, 1285, 1286
CONTAK TR	1241
VIRTUS PLUS II	1380, 1480
INTELIS II	1483, 1484, 1485, 1384, 1385, 1349, 1499

A list of affected devices specific to your clinic accompanies this communication.

Many of these devices are nearing or have exceeded their estimated longevity and have thus outlived their warranty. Even if a device is no longer covered by warranty, Guidant will provide a replacement device at no charge for pacemaker-dependent patients and other patients deemed by their physicians to be best served by replacement, provided the replacement occurs prior to the normal appearance of elective replacement indicators. This supplemental warranty program is available through December 31, 2005. Additionally, Guidant will reimburse patients up to $2,500 for medical expenses remaining after Medicare and/or health insurance coverage, including device replacement or additional follow-up procedures.

Guidant recognizes the impact of this communication on both you and your patients, and wants to reassure you that patient safety remains Guidant's primary concern. As always, if you have any questions regarding this communication, please contact your local Guidant representative or Guidant Technical Services at 1-800-CARDIAC (1-800-227-3422).

Sincerely,

Allan Gorsett
Vice President, Reliability and Quality Assurance
Guidant Cardiac Rhythm Management