URGENT MEDICAL DEVICE SAFETY INFORMATION & CORRECTIVE ACTION

January 21, 2006

Regarding: Two subsets of PULSAR® MAX, PULSAR, DISCOVERY®, MERIDIAN®, PULSAR MAX II, DISCOVERY II, VIRTUS® Plus II, INTELIS® II and CONTAK® TR implantable pacemakers

Dear Doctor,

This letter is intended to inform you of important safety information regarding the potential for loss of therapy due to hermetic seal degradation in two subsets of PULSAR MAX, PULSAR, DISCOVERY, MERIDIAN, PULSAR MAX II, DISCOVERY II, VIRTUS Plus II, INTELIS II and CONTAK TR pacemakers. This letter advises physicians about potential unanticipated device behaviors and is intended to limit adverse events.

Guidant previously communicated information regarding hermetic seal degradation in a subset of the above pacemakers in a physician letter dated July 18, 2005. Since that time, the projected rate of occurrence has increased for this advisory population. In addition, Guidant has identified a second population of devices outside of the advisory population that may also be susceptible to hermetic seal degradation. Our records indicate that you have implanted or are monitoring patients with devices from one or both of these populations. The United States Food and Drug Administration (FDA) classified the July 18, 2005 physician letter as a Class I recall and has indicated this communication may be classified as an expansion of that recall.

Summary of the July 18, 2005 Physician Letter

As described in the July 18, 2005 letter to physicians, Guidant's Quality System determined that a hermetic sealing component utilized in 78,000 devices manufactured between November 25, 1997 and October 26, 2000 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 device 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 Clinical Notes**:*

1) *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.*
2) *While inappropriate accelerometer function has been observed in 45% of the failures reported to date, it cannot be relied upon as an early indicator of this failure mode.*
3) *While disabling accelerometer function will mitigate inappropriate MSR pacing, moisture penetration can still cause the other behaviors described above, including loss of output.*

Advisory Population Update

Observed rate of occurrence:* Guidant has further defined the advisory population as 77,500 devices manufactured between October 27, 1997 and October 26, 2000. Since the July 18, 2005 physician letter, Guidant has identified 76 additional devices that may have exhibited hermetic seal degradation. Seventy-one (71) of those devices have been confirmed through laboratory analysis to have exhibited hermetic seal degradation; two devices are currently undergoing analysis; three devices may have experienced hermetic seal degradation but were not returned to Guidant for confirmation. A total of 145 reported incidents out of 77,500 devices represents a rate of occurrence of 0.19%. It is estimated that 16,000 devices in this population remain implanted worldwide.

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Clinical implications: As of January 9, 2006, Guidant has confirmed a total of 71 reports of loss of pacing output, including ten patients who experienced syncope and two instances of cardiac arrest with resuscitation. Loss of pacing output has also been associated with reports of presyncope requiring hospitalization. Guidant has received 65 reports of Maximum Sensor Rate (MSR) pacing associated with hermetic seal degradation. Sustained MSR pacing has been associated with one report of myocardial infarction, two reports of possible development of heart failure, and five reports of shortness of breath that could be indicative of heart failure. As reported in the July 18, 2005 physician letter, one patient whose device exhibited sustained MSR pacing was admitted to the hospital with multiple health issues and later expired. It is unknown if the device experienced hermetic seal degradation as the device was not returned and hermetic seal degradation could not be confirmed.

Projected rate of occurrence:† Based on further investigation and laboratory analysis of returned devices, Guidant's projected rate of occurrence for reported events within the remaining lifetime of active devices is now estimated to be between 0.31% and 0.88%, which has increased from the July 18, 2005 estimate of between 0.17% and 0.51%.

Second Population

Since our July 18, 2005 physician letter, Guidant has identified a second population of 54,000 devices manufactured between October 19, 1998 and December 5, 2000 that are at risk of hermetic seal degradation, though at a much lower rate than the advisory population. Guidant identified this second population after investigating reports of five pacemakers outside the advisory population exhibiting clinical behaviors similar to those described in the July 18, 2005 physician letter. At the time devices in the second population were assembled, hermetic sealing components susceptible to gradual degradation were mistakenly mixed with a much larger group of non-susceptible components. Within the second population of 54,000 devices, Guidant has identified by model number and date-of-manufacture approximately 2,500 devices with susceptible components, but is unable to identify susceptible devices by serial number. Additional information

Observed rate of occurrence:* As of January 9, 2006, two devices in the second population have been confirmed to have exhibited hermetic seal degradation; three devices may have exhibited hermetic seal degradation but have not been returned to Guidant for confirmation. A total of five reported incidents out of 54,000 represents a rate of occurrence of 0.009%. It is estimated that 19,300 devices in this second population remain implanted worldwide.

Clinical implications: As of January 9, 2006, Guidant has confirmed two reports of loss of pacing output, including one patient who required hospitalization for presyncope and chest pain. Three devices exhibited high rate MSR pacing and remain implanted.

Projected rate of occurrence:† If a device in the second population has a susceptible component, it is subject to a risk of hermetic seal degradation equal to that of the original population. However, because devices with a susceptible component cannot be specifically identified and are distributed among the 54,000 devices in the second population, the projected rate of occurrence for reported events within the second population is substantially lower than the projected rate of occurrence for the original advisory population. For the remaining lifetime of active devices, the projected rate of occurrence for reported events within the second population is estimated to be between 0.02% and 0.06%.

* The number of actual clinical incidents may be greater than the number reported to Guidant.

† Assumes that devices remain implanted through normal replacement indicators. Predictive modeling is inherently uncertain due to its dependence on the device age distribution of reported events and resultant statistical approximations and assumptions.

Recommendations

Original advisory population

Guidant's original patient management recommendations from the July 18, 2005 physician letter remain unchanged. When determining the most appropriate patient management option, physician 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 that physicians reassess their patients in light of the increased projected rate of occurrence.***

- 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 and potential clinical consequences of sustained rapid heart rate.
- 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:
    - o Evaluate for the clinical behaviors described above.
    - o Evaluate battery status indicator ("gas gauge") for signs of early or rapid depletion between sequential follow-up visits.
    - o 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 (i.e., 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.

Second/new population
Physicians should consider the above recommendations while taking into account the lower projected rate of occurrence and the unique needs of each individual patient, including pacemaker dependency, when making patient management decisions for patients in the second population.

Warranty Supplement Program
Guidant's warranty supplement program, subject to certain conditions, provides a no cost replacement device and up to $2500 in unreimbursed medical expenses. The program is available through June 30, 2006 and is applicable to both populations.

Model Numbers Affected
Both populations include the following model numbers:

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

A list of advisory population devices and a list of second population devices, both specific to your clinic, are enclosed. A device model/serial number look-up/search tool is also available at www.guidant.com in the Product Safety Information section.

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 (227-3422).

Sincerely,

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Vice President, Reliability and Quality Assurance
Guidant Cardiac Rhythm Management