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FDA Announces Guidant's Class I Pacemaker Recall

The U.S. Food and Drug Administration (FDA) is notifying health care providers and patients that Guidant Corporation is voluntarily recalling certain pacemakers. A seal within the devices can leak, allowing moisture to affect the electronic circuits. This defect can cause the pacemakers to fail to provide pacing or can cause a rapid heart rate. Other unexpected device behaviors are also possible. The problems may occur without warning and can lead to loss of consciousness, and possibly heart failure and death.

Only the following models are affected by this recall. All were manufactured between November 25, 1997 and October 26, 2000.

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

** VIRTUS PLUS II and INTELIS II models available only outside the U.S.*

Guidant announced the initiation of a voluntary recall on July 18, 2005. The recall action consisted of a letter to physicians that describes the problem and provides recommendations about how to minimize the risk of pacemaker failure.

The FDA has classified Guidant's action as a Class I recall. Recall classifications can fall into one of three categories, with Class I being the most serious. These numerical classifications are based on the probability that the device failure could lead to adverse health effects. In a Class I recall, there is a reasonable probability that the malfunctioning device will cause serious adverse health consequences or death.

"Pacemakers are complex medical devices that can extend and improve the lives of many people who have heart rate abnormalities. However, they are not perfect and can malfunction," said Daniel Schultz, M.D., Director, FDA's Center for Devices and Radiological Health. "We are notifying patients and physicians about this important safety matter so they can take prompt action to reduce the risk of serious health consequences."

Some patients are very dependent on pacemakers to maintain an adequate heart rate. For

these patients, failure of the device to provide pacing output can cause sudden faintness or loss of consciousness, and can result in death. The leakage defect can also cause a sustained rapid heart rate, which can cause heart failure and result in death.

While the failures can occur without warning, sometimes a leak-related malfunction can be detected by a physician before the malfunction causes serious problems. Guidant has provided information to physicians about ways to identify a leak-related malfunction. However, Guidant is not aware of any test that will show if a normally functioning pacemaker is likely to fail in the future.

As of July 11, 2005, Guidant had received reports that 69 pacemakers may have failed because of the leakage. Twenty of the devices were confirmed to have stopped providing pacing output, resulting in loss of consciousness in five patients. Guidant also received reports of two patients who had sustained pacing at a rapid rate. A patient whose device exhibited sustained pacing at a rapid rate was admitted to the hospital and later died. The device problem could not be confirmed as leakage since the device was not returned.

Approximately 18,000 of the affected devices remain in service in the United States and an additional 10,000 are in service in other countries. Guidant estimates that the failure rate from the leakage defect will be between 0.17% and 0.51% (i.e., between 1.7 per one thousand and 5.1 per one thousand) over the remaining lifetime of the devices. It is possible that the actual failure rate will be greater than this, in part, because some past failures may not have been reported to Guidant.

The FDA is not making a recommendation about whether a patient who has one of the Guidant pacemakers affected by this recall should have it replaced. This is a decision that should be made by the patient in consultation with his or her physician, based on the patient's history and medical condition. Removal and replacement of the device may pose some risk, so it is important that patients and physicians carefully discuss this matter before making a decision.

The FDA concurs with Guidant's proposed recommendation to patients, which are consistent with the physician recommendations previously set forth in Guidant's July 18 letter:

- If you believe you are pacemaker dependent, contact your physician soon to discuss your treatment options.
- Continue your normal doctor appointments.
- If you experience symptoms of shortness of breath, dizziness, lightheadedness, loss of consciousness, or a prolonged fast heart rate, you should consult with your physician or go to the emergency room immediately.
- If you are not sure which model you have, or if you have other questions regarding your device, you should consult with your physician.
- If you know your device's model and serial number and want to find out if it is affected by the leakage problem, you can check www.guidant.com/webapp/emarketing/lookup.jsp or contact Guidant Technical Services at 1-866-GUIDANT (1-866-484-3268).

If you are a physician or a patient who has experienced a problem with any of these pacemakers, please send a report to FDA's MedWatch program and to Guidant. See http://www.fda.gov/medwatch/ for filing information or call 1-800-FDA-1088 (1-800-332-1088).

Guidant has posted information for physicians on its web site at www.guidant.com. Information for patients will be posted soon. If you have further questions, you may contact Guidant at 1-866-GUIDANT (1-866-484-3268).

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Guidant Press Release (July 18, 2005)

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