



July 22, 2005

Dear Patient,

We are sending you this letter to make you aware of important information regarding failures of certain Guidant pacemakers manufactured between November 25, 1997 and October 26, 2000. We have identified 69 failures so far in the following pacemaker models:

- PULSAR<sup>®</sup> MAX Models 1170, 1171, 1270
- PULSAR Models 0470, 0870, 0970, 0972, 1172, 1272
- DISCOVERY<sup>®</sup> Models 1174, 1175, 1273, 1274, 1275
- MERIDIAN<sup>®</sup> 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<sup>®</sup> Model 1241
- VIRTUS PLUS<sup>®</sup> 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 recently determined that a gradual degrading of a seal used in these devices results in a higher than normal amount of moisture entering the pacemaker case. The failures all occurred after the pacemakers had been used for at least 44 months. As a result of the failures, several patients lost consciousness or developed possible heart failure. There are about 28,000 of these devices in use worldwide. About 18,000 are in use in the United States.

We are providing you with this information so that you will be better able to discuss treatment options with your doctor. We have notified your physician of the unlikely, but possible, failure in these devices and have notified the Food and Drug Administration of the problem. We recognize the impact of this communication on you and your family and hope this letter helps answer questions you have regarding your Guidant pacemaker.

## Advice for Patients

- We have recommended that your physician consider increasing the frequency of your visits to check your pacemaker
- For patients who are completely dependent upon their pacemaker, we have advised physicians to consider device replacement. If you are pacemaker dependent, please contact your physician soon to discuss your treatment options.
- If you experience symptoms of shortness of breath, dizziness, lightheadedness or a prolonged fast heart rate, you should consult with your physician or go to an emergency room immediately.
- If you are not sure which model pacemaker you have, or if you have other questions regarding your device, ask your doctor for this information.
- If you know your device's model and serial number and want to find out if it is the affected models, you can access <http://www.guidant.com/lookup/> or contact Guidant Technical Services at 1-866-GUIDANT (1-866-484-3268).

While we cannot recommend any tests to your physician that will predict if a device will fail, follow-up evaluations may help to identify if your device has experienced this problem. If you would like more information from Guidant about your pacemaker, call 1-866-GUIDANT (1-866-484-3268) in the U.S. or visit [www.guidant.com](http://www.guidant.com).

If your physician determines you need a replacement device, Guidant will provide a replacement pacemaker at no charge. Additionally, Guidant will reimburse up to \$2,500 in medical expenses not paid by Medicare or your health insurance. Guidant has sent your physician a letter that contains additional information if a replacement device is needed.

As always, please contact your physician if you have additional questions or concerns. It is our normal process to communicate with physician directly about any updates or additional information.

Sincerely,



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