URGENT MEDICAL DEVICE SAFETY INFORMATION & CORRECTIVE ACTION

July 22, 2005

Update regarding VENTAK PRIZM AVT®, VITALITY® AVT, and CONTAK RENEWAL® AVT

Dear Doctor:

This letter updates previous safety information regarding all serial numbers of VENTAK PRIZM AVT, VITALITY AVT, and CONTAK RENEWAL AVT. Our records indicate that you have implanted or are monitoring patients that have these devices. *Guidant is revising its original recommendations set forth in the June 17, 2005 letter because new information indicates that one of the original recommendations can increase the risk of a latching event.* The FDA may consider this action as a recall.

As described in a June 17, 2005 communication to physicians, Guidant has determined that the atrial therapy (AVT) subgroups of certain Guidant ICD and CRT-D product families are subject to a condition in which functional "latching" limits available therapy. At that time, two occurrences had been confirmed out of approximately 20,950 devices implanted to date.

On July 11, 2005, a third AVT latching event was reported in the United States. Guidant immediately began analysis and has determined that this event occurred despite Atrial Episode Data Storage being programmed to 0%. This resulted in a latched state of continuous pacing at approximately 120 pulses per minute. This third event, similar to the first two events, resulted in no apparent patient injury beyond device replacement. Additional events, including a possible injury, are being evaluated.

Clinical Implications
Latching of AVT devices will suspend detection and treatment of atrial and ventricular arrhythmias. Telemetry, programming and magnet response are not available. Brady pacing may continue, but will not be programmable and may not reflect programmed settings. In a latched state, battery usage may increase, but battery status indicators will not be available. In the event that latching occurs during delivery of ATP therapy, ventricular or atrial ATP therapy delivery could continue independent of patient need. Device replacement is required if latching occurs.

Based on study of the recent third event, **Guidant has determined that one of our original recommendations – programming Atrial Tachy Episode Data Storage to 0% – can cause latching in a subset of AVT devices that have previously stored atrial episode data.** Guidant has determined that this newly observed latching pathway can have a significantly higher probability of occurrence (estimated at 0.086% per month) for devices that have previously stored atrial episode data. For this reason, our recommendations have been altered as follows:

REVISED Recommendations

- Schedule a patient follow-up visit
  - As soon as possible for patients reprogrammed to 0% according to our June 17th recommendation, or any patient with Atrial Episode Data Storage programmed to less than 20%
  - Per normal scheduling if Atrial Episode Data Storage is at the nominal of 50% or is programmed to 20% or more

- At this follow-up visit:
  1) Verify normal device function using routine clinical follow-up procedures
  2) Program Atrial Episode Data Storage to 20%
  3) Review the rate of occurrence estimates in Table 1 to evaluate the additional risk reduction benefit of programming ATP therapy OFF

Table 1 below quantifies the probability of latching associated with each of these programming options.

Important note: **Atrial Episode Data Storage should not be programmed to 0% if the device has previously stored atrial episode data**.

Important note: For some patients for whom atrial episode data has not been previously stored, programming to 0% may afford additional risk reduction. Contact Technical Services for additional information before programming Atrial Episode Data Storage to 0%.

Table 1. Estimated Probability of Device Latching[(1)]

Programming options	**Probability of latching per month**	**Probability of latching per 6 months[(2)]**	**Probability of latching with continuous ATP therapy per 6 months[(2)]**
If atrial episodes have been previously stored ***and*** Atrial Tachy Episode Data Storage is programmed to 0% **[Not recommended]**	0.086% (1 per 1,160)	0.52% (1 per 192)	0.027% (1 per 3,700)
A) At Atrial Tachy Episode Data Storage of 50% (nominal)	0.00083% (1 per 120,000)	0.005% (1 per 20,000)	0.000265% (1 per 377,000)
B) If atrial episodes have been previously stored, program Atrial Tachy Episode Data Storage to 20%	0.00043% (1 per 232,000)	0.0026% (1 per 38,500)	0.00014% (1 per 714,000)
C) Program all ATP therapies to OFF	No change	No change	Zero [(3)]
Following implementation of a software solution in early Q405[(2)]	Zero Return to normal programming	Zero Return to normal programming	Zero Return to normal programming

[(1)] Probabilities are current as of July 21, 2005.

[(2)] While the probabilities are stated over a six month time frame, a software solution may be available in early Q405, pending FDA approval.

[(3)] Although functional latching may still occur, it will not result in continuous ATP therapy.

Devices Impacted
Only atrial therapy AVT subgroups of Guidant ICD and CRT-D product families are impacted by this anomaly. ***This issue does not impact standard ICDs and CRT-Ds.***

Table 2. AVT Models Impacted

Device Family	Model Numbers
VENTAK PRIZM AVT	1900
VITALITY AVT	A135, A155
CONTAK RENEWAL 3 AVT*	M150, M155
CONTAK RENEWAL 3 AVT HE*	M157, M159
CONTAK RENEWAL 4 AVT*	M170, M175
CONTAK RENEWAL 4 AVT HE*	M177, M179

*Under clinical investigation in some geographies.

Updated device lists specific to your clinic will be provided.

Future Actions By Guidant
Guidant is currently developing a non-invasive software solution for VITALITY AVT and all RENEWAL AVT devices. This solution may be available in early fourth quarter, pending regulatory approval. Upon first interrogation with new programmer software, VITALITY AVT and all RENEWAL AVT devices will no longer be subject to this anomaly. At that time, memory may be re-allocated as desired for atrial episode data storage and normal programming can be resumed.

While programming options discussed above will significantly reduce the risks of functional latching in a PRIZM AVT, estimates of normal service life for remaining PRIZM AVTs indicate that few will be in service by the time a software solution can be developed and approved. Accordingly, no software update will be developed for PRIZM AVT.

Further Information
We recognize the impact of this communication on both you and your patients, and want 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
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Guidant Cardiac Rhythm Management