IMPORTANT MEDICAL DEVICE SAFETY INFORMATION & CORRECTIVE ACTION

September 22, 2005

Regarding: Guidant INSIGNIA® and NEXUS® implantable heart pacemakers (see table of models below)

Dear Doctor:

This letter is intended to inform you of important safety information regarding Guidant INSIGNIA and NEXUS implantable heart pacemakers. Our records indicate that you have implanted or are monitoring patients implanted with these devices. The United States Food and Drug Administration (FDA) may classify this communication action as a recall.

Guidant's Cardiac Rhythm Management Quality System has identified two separate failure modes, each occurring at a low rate, being monitored within the INSIGNIA and NEXUS families of implantable pacemakers. One or more of the following device behaviors may be observed:

- Intermittent or permanent loss of pacing output without warning
- Intermittent or permanent loss of telemetry
- Reversion to VVI mode or appearance of a reset warning message upon interrogation

The clinical behaviors associated with these failure modes can result in serious health complications. There have been no reported deaths resulting from these failure modes. Loss of pacing output associated with these failure modes has resulted in syncope as well as presyncope requiring hospitalization.

First Failure Mode
As of September 6, 2005, thirty-six (36) failures associated with a first failure mode have been confirmed out of 49,500 devices distributed worldwide (0.073%). Seven of these devices exhibited no output during the implant procedures. For devices successfully implanted, the majority of failures occurred early in life, with a mean implant time of seven (7) months. This failure mode demonstrates a failure rate that decreases with implant time, and no failures have been reported beyond twenty-two (22) months of service. Guidant has received three (3) reports of syncope and six (6) reports of bradycardia or heart block associated with this failure mode which required emergency hospitalization. One device was determined to have failed briefly and resumed functioning with no indication to the physician detectable during routine follow-up.

Root cause has been identified as foreign material within a crystal timing component. The supplier of the crystal timing component used in this subset has eliminated foreign material within the crystal chamber, and no such failures have been observed in any devices shipped after March 12, 2004.

Guidant's modeling, based on field experience and statistical analysis, predicts the failure rate for the active device population of 41,000 to be between 0.017% to 0.037% over the remaining device lifetime, or approximately seven (7) to fifteen (15) additional failures. An estimated 24,000 are active in the United States.

Recommendations regarding First Failure Mode:
Physicians should consider the projected low and declining failure rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. Guidant recommends normal monitoring, as per device labeling. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness.

Second Failure Mode
As of September 6, 2005, sixteen (16) failures associated with a second failure mode have been confirmed out of 341,000 INSIGNIA and NEXUS devices distributed worldwide (0.0047%). For all sixteen devices, a no output condition was exhibited at the implant procedure or pre-implant testing. Guidant has received one (1) report of a pacemaker-dependent patient experiencing syncope and resuscitated cardiac arrest that occurred in association with loss of pacing output during an elective pulse generator replacement procedure. Root cause analysis is ongoing; a specific root cause for this observation has not yet been determined. An estimated 145,000 of these devices are active in the United States.

Recommendations regarding Second Failure Mode:
Guidant recommends verifying pacemaker operation in the packaging prior to the implant procedure. Devices exhibiting intermittent or permanent loss of output or telemetry should not be implanted.

Physicians should consider both the very low occurrence rate and that no failures have been observed after successful confirmation of pacing at implant, in addition to the unique needs of individual patients, in their medical decisions regarding patient management.

Devices Impacted
The following model numbers are affected by this communication*:

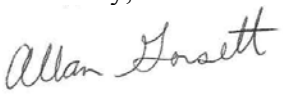
Guidant Pacemakers		Guidant Intermedics Pacemakers	
Device Family	**Model Numbers**	**Device Family**	**Model Numbers**
INSIGNIA Entra SSI	0484, 0485	NEXUS Entra SSI	1325, 1326
INSIGNIA Entra DDD	0985, 0986	NEXUS Entra DDD	1425, 1426
INSIGNIA Entra SR	1195, 1198	NEXUS Entra SR	1395, 1398
INSIGNIA Entra DR	1294, 1295, 1296	NEXUS Entra DR	1466, 1494, 1495
INSIGNIA Ultra SR	1190	NEXUS Ultra SR	1390
INSIGNIA Ultra DR	1290, 1291	NEXUS Ultra DR	1490, 1491
INSIGNIA Plus SR	1194	NEXUS Plus SR	1394
INSIGNIA Plus DR	1297, 1298	NEXUS Plus DR	1467, 1468
INSIGNIA AVT SSI	482	NEXUS AVT SSI	1328
INSIGNIA AVT VDD	882	NEXUS AVT VDD	1428
INSIGNIA AVT DDD	982	NEXUS AVT DDD	1432
INSIGNIA AVT SR	1192	NEXUS AVT SR	1392
INSIGNIA AVT DR	1292	NEXUS AVT DR	1492

*Not all models are available in all geographies.

A list of patients specific to you and your clinic with devices potentially affected by the first failure mode accompanies this communication.

Guidant recognizes the impact of any product performance communication on both you and your patients, and wants to reassure you that patient safety remains Guidant's primary concern. Any updates that become available will be promptly communicated. 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