CARDIAC RHYTHM MANAGEMENT

GUIDANT

Advisory Update

INSIGNIA® and NEXUS®

This is an update to Guidant's September 22, 2005 letter to physicians regarding failures within the INSIGNIA and NEXUS family of pacemakers. This update provides the following information:

- *Summary and Rate of Occurrence Update for "Failure Mode 1"*
- *Summary and Rate of Occurrence Update for "Failure Mode 2"*
- *United States Food and Drug Administration (FDA) Recall Classifications*
- *Product Distribution*
- *Update of Recommended Actions*

Summary and Rate of Occurrence Update for "Failure Mode 1"

As of September 6, 2005, thirty-six (36) failures had been reported to Guidant out of a subset of 49,500 INSIGNIA and NEXUS devices distributed worldwide (0.073%). The majority of these devices exhibited a 'no output' condition during the implant procedure or shortly after implant. Root cause was identified as foreign material within a crystal timing component.

As of November 30, 2005, Guidant has confirmed one (1) additional "Mode 1" failure for a total of thirty-seven (37) failures out of the subset of 49,500 INSIGNIA and NEXUS devices distributed worldwide (0.075%). Most of these failures have occurred at implant or early in life, and demonstrate a failure rate that rapidly decreases with time following implant. Guidant continues to predict the incidence rate for the active device population of approximately 40,000 to be between 0.017% and 0.037% over the remaining device lifetime (no change since the September 22, 2005 physician letter). In our September 22, 2005 physician letter, Guidant stated that this failure mode was associated with three reports of syncope and six reports of bradycardia or heart block; no additional clinical consequences have been reported as of November 30, 2005.

Summary and Rate of Occurrence Update for "Failure Mode 2"

As of September 6, 2005, sixteen (16) failures had been reported to Guidant out of 341,000 INSIGNIA and NEXUS devices distributed worldwide (0.0047%). For all sixteen devices, a 'no output' condition was discovered peri-implant (i.e., at the implant procedure or during pre-implant testing). While a specific root cause had not been determined at that time, no failures had been observed after successful confirmation of pacing at implant.

Root cause for INSIGNIA and NEXUS "Failure Mode 2" has now been identified as a microscopic particle within the crystal timing component used in a subset of 257,000 INSIGNIA and NEXUS devices. Although devices manufactured with this crystal timing component passed all manufacturing tests prior to distribution, in rare instances, mechanical shock conditions such as those experienced during shipping have caused the particle to relocate to a point where it interferes with the crystal and therefore pacemaker operation prior to implant. No "Mode 2" failures have been reported following confirmation of successful implantation.

Guidant has utilized two suppliers for the crystal timing component used in the INSIGNIA and NEXUS pacemaker families. Although the September 22, 2005 letter stated that ***all*** INSIGNIA and NEXUS pacemakers were potentially susceptible to "Failure Mode 2," the recent identification of root cause now allows Guidant to clarify that only a subset of devices that incorporate a crystal timing component from one of the two suppliers are susceptible to "Failure Mode 2." No other INSIGNIA or NEXUS devices are susceptible to "Failure Mode 2." Devices incorporating a crystal timing component from the other supplier are no longer included in this advisory action.

As of November 30, 2005, Guidant has confirmed one (1) additional "Mode 2" failure for a total of seventeen (17) failures out of the subset of 257,000 (0.0066%) INSIGNIA and NEXUS devices manufactured and distributed

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worldwide that utilize a crystal timing component susceptible to “Failure Mode 2.” All seventeen failures were identified before or during the implant procedure. There have been no reports of a “Mode 2” failure in over 3.8 million months of service life accumulated by this subset after successful implantation.

FDA Recall Classification
On November 23, 2005, the FDA classified both “Failure Mode 1” and “Failure Mode 2” issues as described in Guidant’s September 22, 2005 letter to physicians as Class II recalls. A Class II recall is defined by the FDA as a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Product Distribution
In March of 2004, Guidant discontinued shipping from manufacturing facilities INSIGNIA and NEXUS devices susceptible to “Failure Mode 1.”

Guidant has recently discontinued shipping from manufacturing facilities INSIGNIA and NEXUS devices susceptible to “Failure Mode 2.” While Guidant recommends normal monitoring for patients implanted with these devices, Guidant representatives will retrieve and replace remaining hospital inventory with product free from susceptibility to “Mode 2” peri-implant failure.

INSIGNIA and NEXUS devices currently being distributed by Guidant are not subject to either failure mode and therefore are not included in either recall.

Your local sales representative can provide a list of ***all*** INSIGNIA devices specific to your clinic. A device model/serial number look-up/search tool is also available at guidant.com in the Product Safety Information section.

Update of Recommended Actions
- Guidant recommends normal monitoring, as per device labeling, for ***all*** implanted INSIGNIA and NEXUS pacemakers.
- Physicians should consider the projected low and declining INSIGNIA and NEXUS “Mode 1” failure rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness.

Updates regarding these devices will be provided in Guidant CRM Product Performance Reports. If you have any questions, please contact your local Guidant sales representative or Guidant Technical Services.