SN-001

Quality and Safety Branch
9 February 2006

Safety Notice 01

GUIDANT IMPLANTABLE PACEMAKERS

Guidant Australia Pty Ltd has issued an update (25 January 2006) to the Hazard Alert of the 19 July 2005. A brief summary follows.

Issue: Potential loss of therapy due to hermetic seal degradation, resulting in a higher than normal moisture content within the pacemaker case late in the devices service life.

Model Numbers Affected * Not available in Australia and New Zealand

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

Devices manufactured between:	
25 November 1997 & 26 October 2000.	19 October 1998 & 5 December 2000
Number of devices implanted in Australia (as identified by Guidant)	
Approximately 550 devices remain implanted	1375 devices were implanted
Adverse effects:	
Premature battery depletion with resulting loss of telemetry and/or loss of pacing output without warning Inappropriate accelerometer function (if programmed ON) resulting in: • Sustained pacing at the Maximum sensor Rate (MSR) • Lack of appropriate accelerator response during activity • Appearance of reset warning message upon interrogation • Inappropriate early display of replacement indicators	Adverse events are the same but at lower incident rate
Guidant's projected rate of occurrence for reported events for the remaining lifetime of active devices	
Initially estimated to be between 0.17% and 0.51% **Now** estimated to be between 0.31% and 0.88%	Estimated to be between 0.02% and 0.06%

NOTICE

Action Required by:
- Directors of Clinical Operations

Distributed to:
- Directors of Clinical Operations
- Directors of Clinical Governance

We recommend you also inform:
- Chief Executives
- Area Directors of Nursing
- Heads of Cardiac Services
- Cardiologists
- Cardiothoracic Surgeons
- Heads of Biomedical Engineering
- Clinical Products Nurses
- Facility Managers
- Directors of Nursing
- Directors of Supply

For further information :
Contact Guidant Australia on 1800 245 559, or for a copy of the letter go to www.guidant.com/physician_communications/

Quality and Safety Branch
NSW Department of Health

Telephone:
02 9391 9200

email:
quality@doh.health.nsw.gov.au

NSW DEPARTMENT OF HEALTH SUGGEST THE FOLLOWING ACTIONS:

That Directors of Clinical Operations:

1. Ensure that the letter from Guidant has been received,
2. Consider the relevancy of this information to their Area, and If relevant,
3. Ensure appropriate Clinical Risk Management strategies are in place within your Area Health Service to manage the level of risk to patients.

GUIDANT IMPLANTABLE PACEMAKERS

A brief summary of action required by Guidant.

Affected Guidant Implantable Pacemakers:

PULSAR® MAX, PULSAR, DISCOVERY®, MERIDIAN®, PULSAR MAX 11, DISCOVERY 11, CONTAK® TR

Guidant implantable pacemakers manufactured between: 25 November 1997 & 26 October 2000

Guidant recommended actions:

Reassess patients in light of the increased projected rate of occurrence

- Consider replacing devices for pacemaker dependent patients.
- Advise patients of actions to take if they experience syncope or light-headedness or have new or increased symptoms of heart failure.
- Select a suitable MSR setting, given the rare possibility that inappropriate sustained pacing at MSR can occur, or
- Consider programming the accelerometer OFF to prevent inappropriate sustained pacing at MSR and potential consequences of sustained rapid heart rate.
- Consider increasing frequency of programmer follow-ups
- Consider increasing the frequency of transtelephonic monitoring to detect inappropriate sustained MSR pacing and or loss of pacing output.

Guidant implantable pacemakers manufactured between: 19 October 1998 & 5 December 2000

Guidant recommended actions:

Physician assessment of each patient taking into account those recommendations for the original alert population and the lower incidence rate.

Related Information:

For a copy of the letter please go to the following link:

http://www.guidant.com/physician_communications/