ENDOTAK RELIANCE Dual Coil, Active Fixation
Models 0157/0158/0159

Worldwide Distribution: 80,000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	–	–	0
Mechanical	1	1	2
Seal rings	1	1	
Other	–	4	4
Non-patterned	–	4	
WW Confirmed Malfunctions	1	5	6

ENDOTAK RELIANCE Dual Coil, Passive Fixation
Models 0147/0148/0149

Worldwide Distribution: 69,000
Worldwide Confirmed Malfunctions: 15

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	–	–	0
Mechanical	–	1	1
Conductor connection	–	1	
Other	–	14	14
Non-patterned	–	14	
WW Confirmed Malfunctions	0	15	15

ENDOTAK RELIANCE S Single Coil, Active Fixation
Models 0137/0138

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 0

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	–	–	0
Mechanical	–	–	0
Other	–	–	0
WW Confirmed Malfunctions	0	0	0

ENDOTAK RELIANCE S Single Coil, Passive Fixation
Models 0127/0128

Worldwide Distribution: 3,000
Worldwide Confirmed Malfunctions: 1

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	–	–	0
Mechanical	–	–	0
Other	–	1	1
Non-patterned	–	1	1
WW Confirmed Malfunctions	0	1	1

ENDOTAK ENDURANCE EZ
Active Fixation
Models 0154/0155/0156

Worldwide Distribution: 36,000
Worldwide Confirmed Malfunctions: 13

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	2	3	5
†Lead body	1	2	
†Terminal leg insulation	1	1	
Mechanical	1	2	3
†Conductor connection	–	1	
†Serial number label	1	1	
Other	1	4	5
Non-patterned	1	4	
WW Confirmed Malfunctions	4	9	13

ENDOTAK ENDURANCE Rx
Passive Fixation, Steroid Eluting
Models 0144/0145/0146

Worldwide Distribution: 26,000
Worldwide Confirmed Malfunctions: 36

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	2	17	19
†Lead body	1	12	
†Terminal leg insulation	1	5	
Mechanical	–	7	7
†Serial number label	–	1	
†Lead conductor	–	4	
†DF-1 terminal pin	–	1	
†IS-1 terminal pin	–	1	
Other	2	8	10
Non-patterned	2	8	
WW Confirmed Malfunctions	4	32	36

ENDOTAK ENDURANCE Passive Fixation
Models 0134/0135/0136

Worldwide Distribution: 6,000
Worldwide Confirmed Malfunctions: 9

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	–	–	0
Mechanical	1	5	6
[1]DF-1 terminal pin		2	
[2]Yoke component		3	
[2]IS-1 terminal pin	1	–	
Other	1	2	3
Non-patterned	1	2	
WW Confirmed Malfunctions	2	7	9

ENDOTAK DSP Passive Fixation
Models 0094/0095/0125

Worldwide Distribution: 49,000
Worldwide Confirmed Malfunctions: 382

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	12	86	106
[1]Lead body	10	61	
[1]Terminal leg insulation	2	35	
Mechanical	21	235	269
[1]IS-1 terminal pin *(Advisory Issued)*	15	199	
[1]DF-1 terminal pin	1	27	
[1]Serial number label	1	–	
[1]Terminal component	1	2	
[2]Yoke component	1	5	
[1]Lead connector	2	1	
Other	4	14	18
Non-patterned	4	14	
WW Confirmed Malfunctions	37	345	382

ENDOTAK PLUS Passive Fixation
Models 0073/0075/0113/0115

Worldwide Distribution: 5,000
Worldwide Confirmed Malfunctions: 70

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	2	22	24
[1]Lead body	1	21	
[1]Terminal leg insulation	1	1	
Mechanical	2	39	41
[1]Serial number label	1	–	
[1]DF-1 terminal pin	–	8	
[1]Serial number label	–	1	
[1]Lead conductor	–	1	
[1]Lead body	2	5	
[1]Lead conductor	1	–	
[1]IS-1 terminal pin	–	25	
Other	–	4	4
Non-patterned	–	4	
WW Confirmed Malfunctions	4	66	70

ENDOTAK 70 SERIES Passive Fixation
Models 0070/0072/0074

Worldwide Distribution: 9,000
Worldwide Confirmed Malfunctions: 167

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	7	98	105
[4]Lead body	7	92	
[11]Lead body		6	
Mechanical	3	50	53
[5]Lead conductor		22	
[17]Lead body		11	
[18]Lead connector	1	2	
[20]Electrode tip	2	4	
[21]Lead conductor		11	
Other		9	9
Non-patterned		9	
WW Confirmed Malfunctions	10	157	167

ENDOTAK 60 SERIES Passive Fixation
Models 0060/0062/0064

Worldwide Distribution: 14,000
Worldwide Confirmed Malfunctions: 206

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	31	107	138
[4]Lead body	30	95	
[7]Terminal leg insulation		1	
[11]Lead body	1	11	
Mechanical	1	50	51
[16]Serial number label	1	1	
[5]Lead conductor		19	
[17]Lead body		16	
[18]Lead connector	1	5	
[20]Electrode tip		3	
[21]Lead conductor		6	
Other	2	12	14
Non-patterned	2	12	
WW Confirmed Malfunctions	37	169	206

Pacing Leads

FLEXTEND Active Fixation
Models 4086/4087/4088

Worldwide Distribution: 161,000
Worldwide Confirmed Malfunctions: 27

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	2	16	18
*Lead body	2	16	18
Mechanical	–	6	6
*Lead conductor	–	6	6
Other	–	3	3
Non-patterned	–	3	3
WW Confirmed Malfunctions	2	25	27

FINELINE II/FINELINE II Sterox
Passive Fixation (Polyurethane)
Models 4452/4453/4456/4457

Worldwide Distribution: 209,000
Worldwide Confirmed Malfunctions: 7

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	–	7	7
*Lead body	–	7	7
Mechanical	–	–	–
Other	–	–	–
WW Confirmed Malfunctions	0	7	7

FINELINE II EZ/FINELINE II Sterox EZ
Positive Fixation (Polyurethane)
Models 4463/4464/4465/4469/4470/4471

Worldwide Distribution: 359,000
Worldwide Confirmed Malfunctions: 17

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface	1	10	11
*Lead body	1	10	11
Mechanical	–	2	2
*Lead conductor	–	1	1
*Terminal weld	–	1	1
Other	–	4	4
Non-patterned	–	4	4
WW Confirmed Malfunctions	1	16	17

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane)
Models 4477/4478/4479/4480

Worldwide Distribution: 86,000
Worldwide Confirmed Malfunctions: 24

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface			0
Mechanical	20	3	23
*Lead body			
*Lead conductor			
*Insulation			
*Connector pin			
*Connector ring			
*Connector set screw			
*Connector housing			
*Electrode			
*Fixation mechanism			
*Tine			
*Helix			
*Suture sleeve			
*Other			
U-shape	20	3	23
Other		1	1
Non-patterned		1	1
WW Confirmed Malfunctions	20	4	24

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone)
Models 4454/4455/4458/4459

Worldwide Distribution: 67000
Worldwide Confirmed Malfunctions: 8

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface		7	7
*Lead body		7	7
*Insulation			
*Connector pin			
*Connector ring			
*Connector set screw			
*Connector housing			
*Electrode			
*Fixation mechanism			
*Tine			
*Helix			
*Suture sleeve			
*Other			
Mechanical		1	1
*Lead conductor		1	1
Other			0
WW Confirmed Malfunctions	0	8	8

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Silicone)
Models 4466/4467/4468/4472/4473/4474

Worldwide Distribution: 73,000
Worldwide Confirmed Malfunctions: 28

	Without Compromised Therapy	With Compromised Therapy	Total
Lead/Patient Interface		20	20
*Lead body		20	20
*Insulation			
*Connector pin			
*Connector ring			
*Connector set screw			
*Connector housing			
*Electrode			
*Fixation mechanism			
*Tine			
*Helix			
*Suture sleeve			
*Other			
Mechanical		3	3
*Lead conductor		3	3
Other		5	5
Non-patterned		5	5
WW Confirmed Malfunctions	0	28	28

References

Descriptions listed below provide an overview of the clinical observations and/or analysis findings associated with each confirmed lead malfunction pattern listed in this report.

All of the patterns listed are thoroughly investigated and analyzed. As part of Boston Scientific's process of continuous improvement, when possible, changes have been or will be implemented in response to identified malfunction patterns. "Improvements implemented" may include product design changes in existing or subsequent generations, manufacturing process modifications, educational communications, labeling changes, etc. Improvement implementation may vary by geography due to various factors, including regulatory review timing, and may not completely mitigate or eliminate the potential for additional malfunctions.

[1]**IS-1 terminal pin** – *July 19, 1999 Voluntary Physician Advisory.* Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.

[2]**Conductor connection.** Loss of sensing, loss of pacing, loss of defibrillation output. Improper conductor wire connection. Improvement implemented.

[3]**Seal rings.** Insertion difficulty at implant, difficulty removing lead from header post-implant. Proximal silicone seal rings not fully adhered to lead terminal. Improvement implemented.

[4]**Serial number label.** Loss of sensing, loss of pacing. Sharp edge in serial number label resulting in breach in outer lead insulation. Improvement implemented.

[5]**Lead body.** Insulation abrasion due to lead-on-lead or lead-on-can contact combined with damage attributed to application of compressive or torsional loads. Damage to lead body may expose conductor.

[6]**Terminal leg insulation.** Loss of sensing, loss of pacing, loss of defibrillation therapy. Abraded insulation on terminal leg portion of lead due to lead-on-lead or lead-on-can contact. Improvement implemented.

[7]**Lead conductor.** Muscle stimulation, inappropriate shocks, oversensing, high pacing impedance, inability to deliver therapy. Repeated flexing, leading to fatigue of lead conductor.

[8]**Lead conductor.** Loss of capture, inability to deliver therapy. Fatigue of lead conductor due to repeated flexing.

[9]**DF-1 terminal pin.** Loss of sensing, loss of pacing, loss of defibrillation output. Compromised insulation and/or conductor integrity from sharp or excessive bending. Improvement implemented.

[10]**Serial number label.** Loss of sensing, loss of pacing. Broken serial number label either due to sharp bend away from header at implant or repetitive movement during implant.

[11]**Terminal component.** Loss of sensing, loss of pacing, terminal pin separation from terminal ring during implant or ICD replacement. Improvement implemented.

[12]**Yoke component.** Noise, impedance anomalies, threshold variation. Use of multiple or pre-formed stylets may cause component within lead yoke to dislodge. Improvement implemented.

[13]**Terminal weld.** Impedance rise, loss of pacing. Loss of connection on terminal weld. Improvement implemented.

[14]**J-shape.** Placement difficulty, dislodgement. Elevated temperatures resulting in a relaxation of pre-formed J-shape. Improvement implemented.

[15]**Lead conductor.** High impedance, loss of sensing, loss of pacing. Variability in wire conductor material. Improvement implemented.

[16]**Lead conductor.** Physical damage to lead conductor, inappropriate shocks, oversensing. Displacement of yoke component due to fatigue of high-voltage lead conductor. Improvement implemented.

[17]**Lead body.** Lead fracture, inappropriate shocks, oversensing. Insulation damage resulting from implant stresses or manufacturing variability.

[18]**Lead connector.** Insulation damage resulting from bending or tension at the terminal connector.

[19]**Lead body.** Physical damage to lead body, inappropriate shocks. Abraded insulation due to contact with patient anatomy.

[20]**Electrode tip.** Separation between electrode tip and lead body.

[21]**Lead conductor.** Physical damage to lead body due to repeated flexing.

[22]**IS-1 terminal pin.** Compromised insulation and/or conductor integrity if lead is bent sharply away from the header block when placed in implant pocket or if pulse generator migrates from implant site. Improvement implemented.

Safety Advisories

This appendix lists in chronological order (from newest to oldest) all relevant safety advisories for which an active device population exists, current as of the date of publication.

Physician and patient letters, as well as *Advisory Updates*, are available at www.guidant.com.

With respect to the number of reported events listed in the summaries below, Guidant recognizes that the actual number of clinical malfunctions may be greater than the number actually reported.

Additionally, rate projections are provided with the acknowledgement that predictive modeling is inherently uncertain due to its dependence on the device age distribution of reported events and resultant statistical approximations and assumptions.

Advisory notifications may vary by geography, based upon local regulatory requirements. Please contact the local Guidant office for more information. Not all products may be approved for use in all geographies, as product approval is geography specific.

PRODUCT

Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this safety advisory is available at www.guidant.com.

INSIGNIA Entra
Models 0484/0485/0985/0986/ 1195/1198/1294/1295/1296

INSIGNIA Ultra
Models 1190/1290/1291

INSIGNIA Plus
Models 1194/1297/1298

INSIGNIA AVT
Models
0482/0882/0982/1192/1292

NEXUS Entra
Models 1325/1326/1395/1398/ 1426/1466/1494/1495

NEXUS Ultra
Models 1390/1490/1491

NEXUS Plus
Models 1394/1467/1468

NEXUS AVT
Models
1328/1428/1432/1392/1492

CONTAK RENEWAL TR
H120/H125

CONTAK RENEWAL TR 2
H140/H145

VENTAK PRIZM 2 VR/DR
1860/1861

VITALITY VR/DR
1870/1871

VITALITY DS DR/VR
Models T125/T135

VITALITY EL DR
T127

VITALITY 2 DR/VR
Models T165/T175

VITALITY 2 EL DR/VR
Models T167/T177

Physician and patient letters are available at www.guidant.com

ORIGINAL COMMUNICATION **23-Jun-06**

Voluntary Physician Advisory
FDA Classification: Class II

Devices within a well-defined subset manufactured using low-voltage capacitors from a single component supplier may perform in a manner that leads to device malfunction, including intermittent or permanent loss of output or telemetry, or premature battery depletion. At the time of the original June 23, 2006 communication, approximately 49,800 devices had been distributed, and approximately 27,200 devices had been implanted worldwide. Guidant initiated retrieval of all non-implanted devices within this subset from hospital and sales force inventory. An Advisory Update was issued on August 24, 2006, with a revised estimation of the implanted population to be approximately 31,000. No inventory from this subset remains available for implant.

Reported Events (worldwide)

At the time of the original June 23, 2006 communication, a total of five (5) devices had been confirmed to have malfunctioned. As reported in the August 24, 2006 Advisory Update, five (5) additional malfunctions have been confirmed since the original June 23, 2006 communication. A total of 10 confirmed malfunctions represent 0.032% of the implanted population of approximately 31,000 devices. Seven (7) of 10 malfunctions were identified while implanted, and three were identified prior to the implant procedure. There have been no reports of patient death associated with this issue. There has been a total of three (3) reports of patients experiencing syncope associated with loss of pacing.

Returned Product Testing (worldwide) As reported in the August 24, 2006 Advisory Update, as of August 18, 2006:

- 13,857 devices were tested from non-implanted inventory containing a capacitor potentially susceptible to degradation. Analysis identified five (5) capacitor malfunctions, which represents 0.036% of devices tested.
- Returned products represent a small and non-random sample of the implanted population and may not be representative of the remaining active device population.

Projected Rate of Occurrence

While a statistically significant projection of expected failures for implanted devices is not possible at this time, testing to date suggests that the frequency of new malfunctions will continue to decrease in the future.

CURRENT RECOMMENDATION **24-August-06**

- Boston Scientific believes that for most patients, normal monitoring according to device labeling is a reasonable course of action.
- Physicians should consider the low and declining device failure rate in addition to the unique needs of individual patients when making medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness.
- Should the device exhibit symptoms described in the table below, please contact your local sales representative or Technical Services for assistance with device evaluation.

	Pacemakers INSIGNIA/NEXUS	**CRT-Ps RENEWAL TR/TR2**	**ICDs VENTAK PRIZM 2, VITALITY and VITALITY 2**
Device Behavior	• intermittent or permanent loss of pacing output • inability to interrogate • erased values in Daily Measurements • ERT or EOL indicator message displayed earlier than expected • a gas gauge less than BOL within six months of implant	• ERI or EOL indicator message displayed earlier than expected • Fault Code 11 message (high current indicator) • a gas gauge less than BOL within six months of implant	• ERI or EOL indicator message displayed earlier than expected • a battery voltage less than 3.10V within six months of implant

PRODUCT	ORIGINAL COMMUNICATION **12-May-06**
Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this safety advisory is available at www.guidant.com. **VITALITY DS DR/VR** Models T125/T135 **VITALITY AVT** Model A155 **VITALITY 2 DR/VR** Models T165/T175 **CONTAK RENEWAL 3** Models H170/H175 **CONTAK RENEWAL 3 HE** Models H177/H179 **CONTAK RENEWAL 4** Models H190/H195 **CONTAK RENEWAL 4 HE** Model H199 **CONTAK RENEWAL 4 AVT** Models M170/M175 **CONTAK RENEWAL 4 AVT HE** Model M177 *Physician and patient letters are available at www.guidant.com*	Voluntary Physician Advisory FDA Classification: Class II Devices manufactured using a single lot of low-voltage capacitors from a single supplier may experience premature battery depletion due to compromised capacitor function. With the accelerated battery use seen in some devices in this population, device replacement indicators continue to function as expected and the device continues to operate normally. However, longevity and time between elective replacement indicator (ERI) and End of Life (EOL) may be significantly shortened. To date, there have been no patient deaths or serious injuries other than device replacement associated with the confirmed premature depletions. Only devices manufactured with capacitors from this supplier's lot (996 devices implanted which is less than 1% of all implants from these device families) have exhibited an increased probability of premature battery depletion. No devices manufactured with components from this lot remain available for implant. *Reported Events* As of May 8, 2006, a total of 76 devices that may have exhibited this failure mode has been reported to Guidant. Of those, thirty (30) such failures have been confirmed. *Rate of Occurance* A total of 76 reported events represents 7.6% of the 996 devices implanted worldwide that utilize a capacitor from this single manufacturing lot. To date, 14 devices were identified at implant, while the average age of implanted devices at the time of detection was 9.3 months and ranged from 5 to 12 months. **CURRENT STATUS 07-Jul-06** Patient management recommendations from the May 12, 2006 physician communication remain unchanged and are provided below under CURRENT RECOMMENDATION. *Reported Events (worldwide)* - 39 additional malfunctions have been identified since the original May 12, 2006 communication. - A total of 69 malfunctions has been confirmed out of the 996 devices manufactured with capacitors from the specified lot. - There have been no reported patient deaths. *Rate of Occurance* A total of 69 confirmed malfunctions represents 7% of the 996 devices implanted worldwide that utilize a capacitor from this single manufacturing lot. To date, 14 devices were identified at implant, while the average age of implanted devices at the time of detection was 10.0 months and ranged from 5 to 13 months. *Analysis of Patient Data Disks* Of the 996 devices in this subset, 582 have had "save to disk" data analyzed. Of these, 75% exhibited some degree of premature battery depletion. To date, the shortest observed timeframe between ERI and EOL for these devices has been 5 weeks. **CURRENT RECOMMENDATION 07-Jul-06** - An in-clinic follow-up should have happened for all patients with implanted devices in this subset. - In addition to normal follow-up, physicians should have contacted Guidant Technical Services at 1-800-CARDIAC (227-3422) for instructions on performing a baseline "save to disk." Data from this interrogation allows Guidant to analyze device memory data, estimate remaining longevity, and provide individualized follow-up and replacement guidelines. Physicians will be notified of disk analysis findings and provided with specific recommendations for individual devices. - For devices in which save to disk data analysis shows *normal* battery depletion, Guidant recommends: • Normal follow-up • Activation of the programmable feature "Beep When ERI is Reached" • Continued "save to disk" operations at each patient follow-up visit to facilitate continuous assessment of battery performance for that device - For devices in which save to disk data analysis shows *premature* battery depletion, Guidant recommends: • Monthly follow-up visits • Activation of the programmable feature "Beep When ERI is Reached" • Continued "save to disk" operations at each patient follow-up visit to facilitate continuous assessment of battery performance for that device. Some variation in estimates can be expected due to variation in device usage from follow-up to follow-up. • Consideration for device replacement any time prior to ERI based on individual patient condition.

PRODUCT

A serialized search tool to determine if a specific device is affected by this safety advisory is available at www.guidant.com.

Among affected serial numbers, only devices implanted subpectorally with the serial number facing the ribs are included in the affected population.

VITALITY HE
Model T180

CONTAK RENEWAL 3
Models H170/H173/H175

CONTAK RENEWAL 3 HE
Models H177/H179

CONTAK RENEWAL 3 AVT
Models M150/M155

CONTAK RENEWAL 3 AVT HE
Models M157/M159

CONTAK RENEWAL 4
Models H190/H195

CONTAK RENEWAL 4 HE
Models H197/H199

CONTAK RENEWAL 4 AVT
Models M170/M175

CONTAK RENEWAL 4 AVT HE
Models M177/M179

Physician and patient letters are available at www.guidant.com

ORIGINAL COMMUNICATION **12-May-06**

Voluntary Physician Advisory
FDA Classification: Class II

Accelerated life testing has confirmed that repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction only if the device is ***implanted subpectorally with the serial number facing the ribs (leads exiting the pulse generator in a clockwise fashion).*** An anterior/posterior (AP) radiograph can be used to determine device orientation. Due to component location, damage associated with this failure mode will not occur in a subcutaneous position or in a subpectoral position with the serial number facing up or in a subcutaneous position.

This failure mechanism can result in one or more of the following device behaviors:
- Loss of shock therapy
- Loss of pacing therapy (intermittent or permanent)
- Loss of telemetry communications
- Beeping (16 tones every six hours), and a programmer warning screen upon interrogation

Reported Events

Two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs) for VITALITY HE ICDs, and CONTAK RENEWAL 3 and 4 CRT-Ds have been received. To date, no patient deaths related to this issue have been reported. One patient required external pacing and immediate device replacement due to lack of pacing therapy. The vast majority of VITALITY HE ICDs and CONTAK RENEWAL 3 and 4 CRT-Ds are implanted subcutaneously and are not subject to this failure mechanism.

Rate of Occurrence

The implant orientation of devices is not reported to Guidant. For this reason, no rate of occurrence or failure rate projection can be provided. However, based on information available to Guidant, it is estimated that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.

The following factors may also impact the risk of failure:
- Exact location of the patient's ribs relative to the pulse generator case
- Body size/muscle mass of the patient (risk increases for larger patients)
- Activity level and/or occupation of the patient (risk increases for more active patients)
- Duration of implant (the risk of component damage increases as devices age, due to repetitive rib stress)

CURRENT STATUS **07-Jul-06**

Patient management recommendations from the May 12, 2006 physician communication remain unchanged and are provided below under CURRENT RECOMMENDATION.

Reported Events (worldwide)

- No additional malfunctions have been identified since the original May 12, 2006 communication.
- A total of two (2) malfunctions has been confirmed; both of these malfunctions occurred in devices implanted subpectorally.
- There have been no reported patient deaths.

CURRENT RECOMMENDATION **07-Jul-06**

Review records to determine if the device is subpectoral.

- For patients with a subpectoral implant, use an AP radiograph to determine device orientation.
- If the device is in a susceptible orientation, the patient should be advised of the potential for device failure, and patient follow-up at least once per quarter is recommended in accordance with device labeling.
- Consider device replacement for muscular or active patients or for patients who regularly need device therapy.
- If the patient's device was implanted subpectorally and leads exit the pulse generator in a **counter clockwise** direction, no change to your current patient management is necessary.
- For future implants, when using subpectoral implantation of a device from any product family listed, orient the device with the serial number facing away from the ribs.

PRODUCT

CONTAK RENEWAL 3 RF
Models H210/H215

CONTAK RENEWAL 3 RF HE
Models H217/H219

CONTAK RENEWAL 4 RF
Models H230/H235

CONTAK RENEWAL 4 RF HE
Model H239

Physician and patient letters are available at www.guidant.com

ORIGINAL COMMUNICATION **11-Mar-06**

Voluntary Physician Advisory
FDA Classification: Class III

Unexpected and sustained low level current occurring only during storage/shipment mode can result in lower than expected battery voltage prior to implant. Guidant has received a total of thirty-nine (39) such reports; none of the devices associated with these reports were implanted.

This low level, non-sustained current may also occur transiently in normal use post-implant, with negligible impact on longevity (less than two weeks over a device lifetime) and no impact on device function. Of the approximately 4,000 devices implanted to date, no reports of abnormal battery voltage for this reason have been received.

CURRENT STATUS **07-Jul-06**

Patient management recommendations from the March 11, 2006 physician communication remain unchanged and are provided below under CURRENT RECOMMENDATION.

Reported Events (worldwide)

Pre-implant—134 additional reports have been received since the original March 11, 2006 communication. A total of 173 occurrences has been reported to Guidant. There have been no reported patient deaths.

Post-implant—No reports have been received by Guidant, and there have been no reported patient deaths.

CURRENT RECOMMENDATION **07-Jul-06**

Pre-implant—Always check battery voltage when preparing for the implant procedure. Devices should exhibit a BOL battery voltage that is typically greater than 3.13 volts (no more than 0.1 volts below the voltage that appears on the package labeling).

Post-implant—Normal follow-up.