IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

In re: Guidant Corp. Implantable Defibrillators Products Liability Litigation	MDL No. 05-1708 (DFW/AJB)
This Document Relates to: Leopoldo Duron, Jr. vs. Guidant Corp., et. al.	

EXHIBIT INDEX
TO DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT REGARDING PLAINTIFF'S CAUSE OF ACTION FOR STRICT PRODUCT LIABILITY (DESIGN DEFECT)

Ex. No.	Description	Pages
A.	**Filed under seal** Relevant excerpts of testimony from the Deposition of Plaintiff Leopoldo Duron, Jr. (75:18-24, 76:1-18), taken on July 6, 2006, including Exhibit 5 attached thereto	0001-0006
B.	**Filed under seal** Plaintiff's "Corrected" Expert Affidavit of Geddes Frank Owen Tyers, M.D., dated March 19, 2007 and the Exhibit labeled as Exhibit D and attached thereto	0007-0035

Dated: April 2, 2007

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

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EXHIBIT A

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

THIRD DIVISION

In re: GUIDANT CORPORATION IMPLANTABLE DEFIBRILLATORS PRODUCTS LIABILITY LITIGATION	MDL No. 05-1708 (DWF/AJB)
This Document Relates to: Leopoldo Duron, v. Case No. 06-00025 Guidant Corporation, et al.	

VIDEOTAPED DEPOSITION OF:

LEOPOLDO DURON, JR.

Thursday, July 6, 2006; 10:09 a.m.

Reported by: Victoria A. Guerrero, CSR No. 8370

something to give him permission, I guess, but I don't recall.

Q Did he talk to you about any risks or side effects to have the surgery to implant the defibrillator?

A No.

MR. SCHULTZ: Go off the record.

MR. NORTHRIP: We'll go off the record.

THE VIDEOGRAPHER: Videotape deposition's off record at 12:14 p.m. This concludes Tape No. 1 in today's deposition.

(Lunch break taken.)

THE VIDEOGRAPHER: Good afternoon. The videotaped deposition of Leopoldo Duron, Jr., taking place at 450 Newport Center Drive on the second floor, Newport Beach, California, on Thursday, July 6, 2006, regarding the Guidant Corporation Implantable defibrillators products liability litigation, MDL No. 05-1708 (DWF/AJB), is now back on the record at 12:55 p.m.

This begins Tape No. 2 in today's deposition. My name is Danny Colohan with Dean Jones Attorney Video Services of Los Angeles and Santa Ana, California.

BY MR. NORTHRIP:

Q Mr. Duron, did you have a nice lunch?

A I sure did. Thank you.

Q I'm glad. Before we broke for lunch we were talking about when you saw the video discussing defibrillators shown to you by Dr. Higgins.

You mentioned that your family was there and that everyone agreed that you should have the defibrillator put in.

Was there any dissent at all? Did anyone voice any alternative opinion?

A No, other than someone, I don't know, one of my daughters might have said you have to go through surgery again, dad. Something like that. But I -- everybody else was in favor.

(Duron Exhibit 5 was marked for identification by the Certified Shorthand Reporter and a copy is attached hereto.)

BY MR. NORTHRIP:

Q Mr. Duron, you've now been handed what's been marked as Exhibit 5 which is a medical record of yours. Take a minute to look at it and see if it's something you've ever seen. Operative report on 3-9, 2002.

MR. SCHULTZ: I think he's sufficiently familiar with it, if you want to direct him to a question.

///

BY MR. NORTHRIP:

Q Sure. Just, is it something you've seen before?

A Yes. I'm pretty sure -- let me see here. Not this page here, but the other page. I'm not sure I have seen this or not.

Q Okay. I'm going to represent to you that it's one of the medical records that was produced by your counsel to us, I believe, yesterday or the day before, very recently. And it identifies itself, if you look at the very top, from Scripps Memorial Hospital in LaJolla; is that right?

A Right.

Q And I'm going to represent to you that this is a report that was done by Dr. Higgins following your surgery. I'd like to turn your attention to the place in the first page where it says Indications for procedure.

Do you see that there, sir? About middle of the first page.

A Yes.

Q And I'm going to read the first sentence there and I'd like you to, once I finish reading it, let me know if I read it correctly.

Leopoldo Duron is a 68-year-old male, post

aortic valve replacement with atrial and ventricular arrhythmias and an EP study documented inducible ventricular tachycardia as well as an atrial flutter which was ablated.

Did I read that correctly, sir?

A Yes.

Q Did Dr. Higgins ever talk to you about your having atrial and ventricular arrhythmias?

A I don't remember.

Q Do you recall him ever telling you what the significance of atrial or ventricular arrhythmias was?

A Again, I don't remember.

Q Is there anything you're aware of, any documents that would help you remember whether or not you had such a discussion with Dr. Higgins?

A Perhaps, but none of this whole paragraph, I don't remember that.

Q Okay. That's fine. I'm going to now read to you the second and third -- excuse me, the second, third, and fourth sentences in the paragraph. And, again, once I finish reading, I'd like you to let me know if I read them correctly.

An EP study and catheter ablasion were performed yesterday. A dual chamber defibrillator was recommended. The procedure, alternatives, risks,

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This Document Relates to: Leopoldo Duron, v. Case No. 06-00025 Guidant Corporation, et al.	

VIDEOTAPED DEPOSITION OF:

LEOPOLDO DURON, JR.

Thursday, July 6, 2006; 10:09 a.m.

Reported by: Victoria A. Guerrero, CSR No. 8370

Scripps
Memorial Hospital
La Jolla

OPERATIVE REPORT

PATIENT: DURON, LEOPOLDO
MR#: 000000645280 ACCT#: 000035961424

DATE OF OPERATION:
03/09/2002

PROCEDURE PERFORMED:
Dual-chamber implantable defibrillator insertion with intraoperative electrophysiologic study, A to P analysis, lead fluoroscopy, cardioversion, automatic implantable cardioverter-defibrillator testing, automatic implantable cardioverter-defibrillator and pacemaker reprogramming, and dual-chamber pacemaker programming, induction of arrhythmia, cardioversion.

SURGEON:
Steven L. Higgins, M.D.

CARDIAC ELECTROPHYSIOLOGIST:
Steven L. Higgins, M.D.

INDICATIONS FOR PROCEDURE:
Leopoldo Duron is a 68-year-old male, post aortic valve replacement, with atrial and ventricular arrhythmias and an EP study documented inducible ventricular tachycardia as well as an atrial flutter which was ablated. An EP study and catheter ablation were performed yesterday. A dual-chamber defibrillator was recommended. The procedure, alternatives, risks, indications, benefits and potential complications were explained and informed consent obtained.

DESCRIPTION OF PROCEDURE:
The patient was taken to the operating room in a fasting state. General anesthesia was administered by Dr. Michael Martin. The patient was prepped and draped in the usual sterile fashion.

A 6-cm incision was made over the left deltopectoral groove. Blunt dissection was performed with electrocautery. The cephalic vein was identified but was too small for use. An 18-gauge needle was inserted in the left subclavian vein. The guide wire was advanced. A dilator and sheath were inserted. The ventricular lead was positioned in the RV apex in a good location and a good threshold was obtained. The retained guide wire was used for a second dilator and sheath and the atrial lead positioned in the right atrial appendage. Each was secured in place with 2-0 Ethibond and were protected with a suture sleeve.

The pectoralis major muscles were divided. A subpectoral pocket was created. The generator was placed in the pocket posteriorly

Duron EXHIBIT 5
FOR IDENTIFICATION
V. GUERRERO, CSR #8370
7-6-06 WIT: Duron-Vg.

after the leads were attached. Thresholds were repeated and found to be acceptable. The pocket was irrigated with antibiotic solution. Good hemostasis was achieved, despite the INR of 2.1. The pocket was then closed in three layers with 2-0 Monocryl for deep and superficial subcutaneous and 4-0 Monocryl subcuticular. Steri-Strips and a sterile dressing were applied. The patient was transported to the recovery room in stable condition.

Intraoperative AP testing was performed. Thresholds obtained as detailed above. Ventricular fibrillation was induced with T wave shocks and successfully recognized and terminated with 14 and 9 joules. The IACD was programmed as noted below. ATP was activated.

IACD LEAD MODEL INFORMATION:
The IACD generator is a Guidant Ventak Prism II DR, model 1861, serial #226065. The atrial lead is a Guidant Flexstim, model 4087, serial #110923. The ventricular lead is a Guidant Reliance, model 0148, serial #118813.

THRESHOLDS:
The atrial threshold is 0.6 volts at 0.5 msec with a 446-ohm impedance and a 1.8-mV P wave. The ventricular threshold is 0.2 volts at 0.5 msec with a 1059-ohm impedance and a 6.6-mV R wave. The defibrillation threshold is 9 joules and shock impedance 33 ohms.

IACD PROGRAM PARAMETERS:
The IACD is programmed as a two-zone device, rate cutoff 170 ATP for 20 seconds, followed by shock therapy of 9 and then 31 joules. Zone 2 has a rate cutoff of 220, with 9 and then 31 joules. Brady pacing is programmed DDDR, lower rate 70, upper rate 130.

IMPRESSION:
1. Inducible ventricular fibrillation.
2. Defibrillation threshold 9 joules.
3. Implantable automatic cardioverter-defibrillator programmed as a two-zone device, rate cutoff 170, antitachycardia pacing and shock therapy.

COMMENT:
The procedure went well. The patient will be restudied on Monday morning. Likely, he will be ready for discharge at that point. Subsequent follow-up will be scheduled at Kaiser Zion Medical

PATIENT: DURON, LEOPOLDO
DICTATED BY: STEVEN HIGGINS, MD

Center.

KAISER MEDICAL RECORD #1497571

DICTATED BY: STEVEN HIGGINS, MD

SH:EDiX15991 C: 03/09/02 12:34
D: 03/09/02 11:15 T: 03/09/02 12:34 DOCUMENT: 200203091566471100

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STEVEN HIGGINS, MD
KAISER ZION MEDICAL RECORDS

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
THIRD DIVISION

In re: Guidant Corp. Implantable Defibrillators Products Liability Litigation	MDL No. 1708 (DWF/AJB)
This Document Relates to All Actions	

EXPERT AFFIDAVIT OF GEDDES FRANK OWEN TYERS, M.D.

I, Geddes Frank Owen Tyers, M.D., make the following statement under penalties of perjury:

1. I am retained by Plaintiffs in the above captioned action to provide this affidavit in support of their claims and to testify at trial.

I. Background and Qualifications

2. I am a fully trained and Board qualified general surgeon, as well as an American Board and Royal College qualified cardiovascular and thoracic surgeon. I am currently Professor Emeritus at the University of British Columbia and was previously professor and head of the division of cardiovascular and thoracic surgery at the University of British Columbia. Before that, I was professor and head of thoracic surgery at the University of Texas Medical Branch, Galveston, Texas. Prior to that, I was an associate professor of general, vascular and cardiothoracic surgery on the faculty of the Pennsylvania State University, and before that, I served as an instructor in general surgery at the University of Pennsylvania.

3. I first became involved in pacemaker implantation in 1964, during my surgical residency, and have been active in cardiac rhythm management device ("RMD") research since 1965, when I successfully competed for a National Institutes of Health grant to develop the first electromagnetically programmable pacemaker.

4. My first independent transvenous pacer implant was performed in 1967, while I was a chief resident of general surgery at the University of Pennsylvania.

5. I began implanting cardioverter defibrillators in February of 1985.

6. My primary research interests continue to include Cardiac Rhythm Management Devices (CRMDs) and cardiac arrhythmias, plus quality appraisal and quality assurance. I hold several lead and pacemaker patents, and have numerous publications and consultancies in the field. I am a founding member of the North America Society of Pacing and Electrophysiology, (now the Heart Rhythm Society) and was nominated by the Canadian Cardiovascular Society, and served as the cardiovascular physician member of the Canadian Bureau of Medical Devices, Risk Based Stratification Advisory Committee, to assist with development of an improved system for medical device approval. I am a past chairman of the Canadian Cardiovascular Society Medical Devices Review Committee with primary responsibility for evaluation of pacemaking and CV support devices. I am a frequently invited speaker at major North American and international meetings. I have served and continue to serve on a number of professional journal editorial boards and advisory committees. Thus I have personal knowledge of the matters attested to in this affidavit. My curriculum vita is attached hereto as Exhibit A.

7. I am a coauthor of a study in the Journal of Pacing and Clinical Electrophysiology, Volume 24, No. 7, July 2001, entitled "Unexpected ICD Pulse Generator Failure Due to Electronic Circuit Damage Caused by Electrical Overstress" (a copy of which is attached as Exhibit B), and of the study presented to the Heart Rhythm Society last year entitled "Multicenter experience with failed and recalled implantable cardioverter-defibrillator pulse generators", since published in Heart Rhythm 2006: 640-4 (attached as Exhibit C).

8. I believe I am widely acknowledged as a CRMD expert, and continue to receive referrals for the management of complicated cases. I have extensive experience with the implantation of pacemaker and cardioverter defibrillator pulse generators and leads, and I have specific expertise with the management of complex cases and extraction of chronic leads. I am frequently consulted by physicians specializing in the care of these patients and take part in surgeries at the Vancouver General Hospital, and at our Regional Heart Centre at St. Paul's Hospital. I also do occasional CRMD implants in a private clinic, and run a CRMD follow up and consulting clinic at the Hospital of the University of British Columbia.

II. Summary of Opinions

9. It is my opinion that Guidant repeatedly failed to adequately inform patients and physicians of the unanticipated additional health risks that were associated with their ICDs, and in doing so, disregarded medical and ethical norms. In a clinical context, where there are choices involving risks, benefits, and alternative treatment modalities, physicians seek to obtain the informed consent of a patient, and to discuss sufficient medical information to enable the patient to decide whether to accept the recommended treatment. This has recently been codified by the American College of Surgeons but dates back to Hippocrates

10. Based on adverse outcomes, Guidant knew of high-risk defects, but failed to disclose these to physicians, the FDA, and the public. Guidant routinely failed to inform customers of the risks inherent in its product and behaved as if it, and the not the patient's medical care providers, should determine what risks patients needed to know about. In doing so, Guidant made critical information unavailable to both doctors and patients, thus compromising the informed consent process and post-implant management.

III. Defined Terms

11. The defined terms used throughout this affidavit are as follows:

a. "AV" means atrioventricular node;

b. "CRT-D" means an implantable cardiac resynchronization device with a cardioverter-defibrillator;

c. "Defibrillators" means Ventak Prizm 2DR Model 1861, and other implantable cardioverter defibrillators

d. "ICD" means implantable cardioverter defibrillator;

e. "Guidant" means Guidant Corporation;

f. "CRM" means Cardiac Rhythm Management, a subsidiary of Guidant;

g. "PG" means defibrillator pulse generator;

h. "CRMD" means cardiac rhythm management device;

i. "SA" means sino atrial node.

j. 1861 means the Guidant's Ventak Prizm 2 DR

k. A "recalled ICD" was a normally functioning ICD that was prophylatically replaced as the result of a voluntary or FDA-mandated action or advisory by the ICD's manufacturer.

l. An advisory ICD is a recalled ICD that was not replaced prophylactically.

IV. Factual Background

12. The 1861 is an implantable cardioverter defibrillator. When functioning properly, the device detects abnormal cardiac rhythms, i.e. rapid and unsynchronized contractions, and/or rapid, uncoordinated, repetitive excitation of the ventricular heart muscle fibers, that prevent coordinated ventricular contraction; and administers an electrical shock to correct the dysfunction of the heart muscles.

13. Approximately 26,000 patients worldwide were implanted with the pre April 2002 ICDs, and 13,900 patients in the United States were still implanted with these higher risk1861s at the time of the June 17, 2005 notice from Allan Gorsett, VP /Reliability and QA at Guidant CRM.

14. Electrical overstress failure is a general term applied to catastrophic critical electrical component failure(s), caused by the application of a large voltage for a sufficient duration of time.

15. In the documents that I have reviewed, the first failure of an 1861 occurred in a patient on February 1, 2002. The 1861 was explanted, returned to Guidant, and analyzed. Guidant engineers identified the failure mechanism as a short circuit, which occurred in the header while delivering a shock. Guidant engineers determined that preventable, systematic flaws in design and manufacturing caused the failure to deliver a potentially life-saving therapeutic shock, and the subsequent inability to provide pacing therapy.

16. A second 1861 pulse generator, which had also exhibited the same short-circuiting failure mode during February 2002, was returned to Guidant and analyzed.

17. By the time of the first documented patient death in 2005, Guidant had knowledge of, at least, 25 similar 1861 failures in patients, 3 of who had required rescue defibrillation.

18. Further, his death occurred at least three years after the failure mode, which caused the 2005 patient's device to fail, had been analyzed by Guidant engineers, who were sufficiently concerned that a sequence of manufacturing modifications were made the same year.

19. On April 16, 2002, Guidant introduced manufacturing changes to mitigate the problem.

20. On June 14, 2002, Guidant completed a Risk Assessment in which it classified the likelihood of injury occurring from an event as "very likely" (from five to ten percent) and the severity of such an injury as life threatening. It concluded that failure to defibrillate as a result of this systematic malfunction could cause the death of a patient, who could have otherwise been resuscitated by a normally functioning ICD. Notably, the risk assessment does not mention the risk of failure of pacing functions. This may also be life threatening in a pacemaker dependent patient who receives either an appropriate ICD shock or an inappropriate shock delivered as a result of over-sensing, self-terminating ventricular tachycardia (VT) or inaccurate discrimination of VT from supra-ventricular tachycardia.

21. On November 13, 2002, Guidant made additional manufacturing changes to further mitigate the risk of shorting in the header. Thus devices without the defects that caused the 2005 patient death could have been made available to him and his physicians approximately three years earlier.

22. According to the report of the Independent Panel of Guidant Corporation (the "Independent Panel Report"), Guidant continued to ship approximately 1,300 risky 1861s from its in-house inventory, and made no attempt to retrieve the approximately 2,700 unmitigated, but not yet implanted1861s that had been shipped to its sales force or to hospitals.

23. The company did establish an internal "Trend" in mid 2002 to monitor this failure mode, but then closed it in **early 2003**, just before the documentation of six additional similar failures. Initiation of the monitoring was on May 20, 2002; discontinuation was on April 16, 2003. In spite of the flurry of additional failures, the trend was not reopened again until November 5, 2004, and again inexplicably closed on March 1, 2005, even though approximately a dozen, more or less identical, arcing failures were documented during 2004, and failures continued during the brief period of refocused attention.

24. According to reports, Joshua Oukrop, the 2005 patient referred to above, who had received a pre-mitigation 1861, died suddenly on March 14, 2005. His 1861 was explanted post-mortem and confirmed to have failed because of the long known header short defect. The patient's physicians, Drs. Barry Maron and Robert Hauser, concluded that Oukrop died of VT or VF because his 1861 failed to deliver a shock, and they asked Guidant to notify physicians about this failure mode on May 12, 2005. Guidant refused, but offered to work with the physicians to prepare a case report for an electrophysiology journal. Maron and Hauser declined the offer and submitted the case report to *Heart Rhythm*. In addition, they notified the *New York Times*.

25. On the evening of May 23, 2005, the day before the publication of the first *New York Times* article, Guidant sent a letter to physicians stating: "As a result of recent communications from sources other than Guidant Corporation regarding the [1861], we want to provide clarity and assure you that the clinical performance of Guidant's prism 2DR ICD continues to exceed design expectations...". Over the next month, the *New York Times* published a series of related articles. The FDA investigated the malfunction, and I and many other physicians questioned the reliability of pre-mitigation 1861s and expressed serious concern about the delay in notification of appropriate physicians.

26. On June 17, 2005, Guidant sent a second letter in which it indicated that the FDA would classify Guidant's safety notification regarding the 1861 as a recall.

27. On July 15 – 17, 2005, Guidant conducted a meeting with its Medical (physician) Advisory Board.

V. The Heart and Heart Failure

28. The heart is a muscular organ composed of four chambers. During rest and lower levels of activity, a healthy heart beats steadily and rhythmically at a rate in the range of 40 to 80 beats per minute, and pumps about five liters of blood every minute. The blood carries oxygen from the lungs to the entire body and waste back to the lungs, liver and kidneys. Blood returning from the lungs and body enters the thin walled upper two chambers of the heart called atria. The atria pump blood into the two lower thicker walled chambers of the heart called the ventricles. The right ventricle pumps blood to the lungs while the left ventricle pumps blood to all the rest of the body's organs. To keep the body healthy, the heart must circulate a sufficient amount of blood.

29. The heart has an electrical system that keeps the heart beat regular and responsive to physiologic demands, and helps to keep the atrial and then ventricular walls contracting in a sequential, coordinated and nearly simultaneous fashion. As a pump the heart is most efficient in delivering blood when it's rate is maintained within the wide normal range. The heart's electrical system, therefore, is critically important to its normal functioning.

30. Normally the heart's natural pacemaker, the SA node, keeps the heart rate in the normal range by sending out regularly spaced electrical signals. Each electrical signal from the SA node starts an electrical chain reaction that spreads across both atria, causing them to contract and pump blood into the ventricles. This electrical reaction continues from the atria into the ventricles through an area called the AV node or junction. The AV node acts as an electrical gateway to the ventricles, delaying their contraction until they have been filled from and primed by the atria.

31. In some cases, the heart's electrical system functions abnormally. When the heart pumps too quickly it is called a tachyarrhythmia. Bradycardia is the name for the condition when the heart beats too slowly. Both types of abnormal heart rhythms decrease the delivery of blood by the heart and can cause death.

32. Tachyarrhythmia can start in either the atria or the ventricles. When the heart beats too quickly and the signals start in the atria, the tachyarrhythmia is called an atrial tachycardia. Atrial flutter and atrial fibrillation are two of the specific types of atrial tachyarrhythmias. Atrial flutter occurs when the atria pump at a very rapid but regular rate and is generally not life threatening. Atrial fibrillation is an irregular and very rapid heart rhythm, where the atrial walls quiver, instead of contracting and thereby pumping effectively. Blood in the atria may then stagnate and clot, and if the clot brakes loose and travels to the brain, a stroke can result. If the ventricles are able to respond to atrial flutter or fibrillation at a very rapid rate, function of the heart can be seriously compromised.

33. There are two general categories of tachyarrhythmias where the abnormal signals start in the ventricles: ventricular tachycardia and ventricular fibrillation. Ventricular tachycardia describes the ventricles initiating impulses that make the heart beat too quickly. Ventricular contraction is no longer coordinated to follow atrial priming. Additionally, when the heart pumps too fast, the ventricular chambers do not have enough time to fill with blood before the next contraction, which further decreases the amount of blood delivered to the body. In addition to decreasing blood delivery (cardiac output), ventricular tachycardia can cause low blood pressure and may progress to a more serious condition called ventricular fibrillation.

34. When ventricular fibrillation occurs, the walls of the pumping chambers for the lungs and for the rest of the body continuously quiver, rather than periodically contracting many times a minute. The electrical signals are chaotic rather than recurring in a regular and predictable pattern as described in paragraph 32 above. The electrocardiogram shows a continuous, low voltage, saw tooth like pattern rather than distinct episodic electrical activity. As a result blood is no longer transported to the body, which causes an undetectable pulse and blood pressure. Even though the heart muscle is quivering, the patient is described as having a cardiac arrest because there is no cardiac output.

35. Bradycardia, where the heart beats too slowly to meet the body's demands, is usually caused by failure of the SA node to produce a signal, or failure of the AV node and related pathways to allow impulses to pass. The latter condition is known as heart block. As a result the heartbeat slows or stops. The heart can no longer pump enough blood, resulting in syncope, dizziness, shortness of breath, and can cause immediate or eventual death. Clinically this is also called a cardiac arrest and in fact the heart has stopped.

36. Life threatening tachyarrhythmias and bradyarrhythmias often occur without warning. When a cardiac arrest occurs the lack of blood flow to the brain and other body tissues can result in irreversible brain damage and other organ damage, leading to death. While brain death is almost certain within five minutes, restoration of a reliable heart rhythm must be accomplished almost immediately to be effective. Administration of an electrical shock to the heart to reset a functional intrinsic (patient generated) heart rhythm, or a paced rhythm is called defibrillation. The purpose of implantable defibrillators is to provide the necessary restorative shock(s) within a matter of seconds. The longer the delay, the lower the probability of success.

VI. Cardioverter-Defibrillators (ICDs)

37. An ICD is a small electronic device that is now usually implanted within the chest wall, often under the left pectoralis muscle. The ICD's function is to monitor the heart for any abnormal rapid, slow or irregular rhythms. When the heart is beating normally the ICD remains inactive. If the heart develops a life-threatening tachycardia the ICD may immediately delivery an electrical shock, or have been programmed to attempt to terminate the rhythm by antitachycardia pacing, and only delivering electrical shock(s) to the heart, if lower energy therapies fail. The purpose is to attempt to terminate the abnormal rhythm and return the heart to a normal rhythm. Although an ICD does not prevent the occurrence of life-threatening rhythms, it is designed to rapidly terminate them when they occur.

38. The ICD may also be programmed to operate as a pacemaker, so that electrical signals are sent to artificially activate (or pace) the heart when an abnormally slow heartbeat is detected. That function is called or known as bradycardia pacing.

39. An ICD system consists of one or more leads and a defibrillator pulse generator (PG). The leads are insulated wires. They are usually inserted through the venous system and attached to an inner wall of the heart. The free end of each lead is then attached to the connector ports on the defibrillator. The leads receive the heart's electrical signals, and carry those signals from the heart to the defibrillator PG to monitor for natural and abnormal heart rhythms. The leads also carry electrical pulses from the PG back to the heart to help coordinate contractions. Some leads also deliver high-energy electrical shocks from the defibrillator to the heart, after a life-threatening tachycardia occurs.

40. The defibrillator PG is encased in titanium and in includes electronic circuitry, capacitator(s), and a power source. The PG constantly monitors the heart rhythm. The circuit instructs the power cell to charge the capacitor(s) and then to initiate an electrical shock or series of shocks when it determines that a life-threatening heart rhythm has occurred. The electronic circuitry also keeps a record of normal and abnormal heart rhythms and the shock(s) sent by the defibrillator.

VII. ICD Implantation

41. The implantation of an ICD, like the 1861 that is the subject of this case, requires the patient to undergo a surgical procedure. Such a procedure may be done as a day surgery where the patient goes home the same day, or as an inpatient with the patient admitted to hospital overnight or longer. The surgery takes approximately one hour for a single chamber defibrillator implantation [lead(s) terminating only in the right ventricle], or up to several hours for a complex implantation. The procedure usually includes testing of the implanted devices for effectiveness of high voltage defibrillation shocks, which may take from thirty minutes to one hour depending on the device being implanted and the outcome of the test(s). Many of the patients who are subject to complicated or lengthy procedures, have serious underlying medical conditions. Therefore, overnight stays

are common for monitoring, device adjustments (surgical or programming), and continuing medical and drug management. Contemporary ICD implantation procedures may be done under local anesthesia with strong intravenous sedation. However, as the test shocks are quite painful and cause the patient to jump, some patients and physicians may prefer general anesthesia and muscle relaxation.

42. Having an ICD and leads implanted or replaced is not a minor procedure. It is important to understand that risks to an individual patient include both the risks of the surgery and the risks of the sedation or anesthesia. Risks for a potential complication of a procedure are listed in Tables 1 and 2, which are attached hereto as Exhibit E. Anesthesia and sedation related complications can also be life threatening in some instances. On average the risk of any complication listed in the table ranges from less than one percent to greater than ten percent, depending upon the patient, implantor-related experience and technique, and other factors. The risk of death from the anesthesia, and the implantation and testing procedure may range from less than one percent to greater than ten percent. As with the general underreporting of PG and lead failures, procedural risks may be underreported, as hospital stays are often short, whereas North American and international standards require reporting (as procedure related) of all complications occurring within thirty days of the procedure, or during the same hospitalization (no matter how long).

VIII. ICD Explantation

43. The procedure involving explanting just a PG is generally no more risky and often less invasive than the implantation procedure. The risks include those of the implantation procedure listed above. However if removal of leads is also required, and particularly for those implanted over six months, the patient and medical team face a number of additional and unique complexities and potential risks. Lead extraction (removal of a previously implanted and still in place

defibrillator lead) using modern tools, is associated with a greater than one percent directly procedure-related risk of death to the patient, and at least a 2.5% procedure-related risk of potentially life threatening complications. Risks of major complications are higher in female patients, in those patients with several leads in place (usually the case in defibrillator patients), in patients with complex leads (always the case with defibrillator patients) and with longer durations of implant. Procedure-related complications are also higher for surgeons doing a lower volume of extractions (less than fifty per year) and if the extraction is done outside a cardiac surgery OR. Even with the use of state of the art products such as effective locking stylets and powered dissection sheaths, the procedure related risk of death remains significant. Further, the risk of future ICD system re-implantation, which most patients require, is also increased.

IX. ICDs

44. Each year, over 70,000 patients undergo implantation or replacement of ICDs to avoid sudden cardiac death.

45. The ICD is relied upon to detect and terminate potentially lethal ventricular tachyarrhythmias and to provide rate support during bradycardia. Thus, for the individual patient, failure of an ICD pulse generator or lead may be catastrophic. ICD pulse generators are expensive, and replacement surgery is costly and associated with known complications, including infection.

46. Electronic malfunctions of ICD's are unpredictable and may not be detected by standard follow-up techniques before an ICD is unable to deliver effective therapy. Thus, sudden cardiac arrest or death may be the first and only sign that an ICD has failed.

X. Manufacturers' Duty to the Physicians and Patients

47. A fundamental principle underlying the relationship between ICD manufacturers, and the physicians and patients, who rely on their products, is the duty of the manufacturers to provide the physicians and patients with accurate, up-to-date information about the risks and benefits inherent in the use of their devices, so that physicians can properly inform and treat their patients.

48. The medical community is almost totally dependent on the ICD manufacturers to supply timely and accurate information regarding the performance/reliability of their products. Currently, the public's primary source of post-market product performance data is the manufacturers' Product Performance Reports. The FDA's Manufacturers and Users Facility Device Experience (MAUDE) database is not designed to be a routine post-market surveillance tool for physicians or a useful source of information for patients, and may not necessarily be a reliable source of information.

49. Manufacturers must inform doctors and patients when they possess information indicating that a product is defective or poses a serious risk or danger to the patient; and the manufacturer must affirmatively remove such devices from the marketplace in a timely manner. Product Performance Reports by manufacturers should be fully informative, accurate and guided by the principle of what's safest for patients is, in the long run, safest for the corporation. Falling into the trap of focusing on short term marketing and product availability considerations, as appears to have happened with some Guidant personnel, is a lose-lose in the current informed patient and regulatory environment

50. Full disclosure is always critical, and even more so when a life-sustaining device such as an ICD is involved. Doctors cannot make an informed recommendation regarding the best care for a patient, or obtain informed consent from a patient, when a company withholds critical information or provides

misleading information about the safety of a medical device. Patients and their physicians expect and are entitled to full disclosure of product information that may affect an individual's health or safety. This requires manufacturers to maintain a completely open, honest and transparent relationship with the medical community, patients who have received their products, and the FDA.

51. A manufacturer should immediately advise all physicians when it discovers that an ICD, like the 1861, has exhibited a recurring failure mode that will sooner or later be lethal for one or more individuals.

XI. Expectations of the Prescribing and Implanting Physicians

52. The physician patient relationship should be based on trust. Informed consent is crucial to this relationship. As physicians we have a duty to inform our patients of all recognized approaches to care and their risks and dangers. Prior to recommending the implantation of any medical device or other therapeutic modality, it is the duty of each physician to inform every patient of all the known risks, and it is every physician's ongoing duty to advise all patients of any new information that may impact the patient's health.

53. When a medical device manufacturer like Guidant knows that a defect in one of its medical device families may have serious clinical consequences, and that any future patients implanted with a device with similar deficiencies will face similar adverse consequences, reasonable physicians and patients would expect:

(a) The manufacturer to make a substantial effort to determine the likelihood of future failures;

(b) The manufacturer to notify physicians promptly if there is likelihood that this information might alter a clinical recommendation about prescribing this and related medical devices;

(c) The manufacturer to act as expeditiously as possible to retrieve all unimplanted medical devices such as ICDs, with similar design and manufacturing flaws;

(d) The manufacturer to design and manufacture a safer product and to obtain proper test results and regulatory approvals before reintroduction to the market; and

(e) The manufacturer to have selected more reliable materials and processes in the first place,

XII. Guidant Failed in its Duties to Physicians and Patients

54. In the case of failures of the 1861 caused by shorting in the header, Guidant took none of these steps. To the contrary, Guidant withheld information from physicians until the New York Times articles in May of 2005 focused scrutiny on the company. By withholding this information, Guidant denied physicians the information necessary to make sound clinical and follow up recommendations to our patients, and the means to provide our patients with the ongoing information, necessary for them to make intelligent, informed decisions. Guidant's failure to advise physicians of the failures that were observed in the 1861, as well as the potential for future malfunctions, denied us the opportunity to provide our patients with the advice, necessary for them to decide whether or not to undergo explantation of their at risk ICDs. Further, Guidant's conduct denied physicians information that would reasonably have been used in making a judgment on whether or not to recommend new Guidant ICD implants to our patients.

55. As physicians there are facts regarding risks, benefits, and alternatives therapies, that need to be discussed with patients in sufficient detail, to enable them to decide whether or not to accept the recommended treatment; that is to give informed consent.

56. The requirement that physicians obtain informed consent from their patients before treatment is a basic tenant of Western medicine and culture. The duty to obtain informed consent constitutes a part of the standard of care that all physicians must adhere to legally. Given this ethical and legal duty, physicians have a right to know about the performance features of devices and other modalities that may be used in a patient's treatment.

57. Medical device manufacturers owe a duty to adequately warn prescribing physicians about the risk of their products as soon as reasonably possible after a nonrandom defect is uncovered. If a physician is not informed of, or is misled regarding the nature and extent of the risk of a procedure, device or medication, the physician becomes unable to provide the patient, the information that is required to obtain adequate and proper informed consent.

58. For physicians to conduct themselves as learned intermediaries, and for the manufacturer to have properly discharged its duty, the warning provided to a physician must be timely and adequate.

59. Based on clinically and ethically irrelevant statistical calculations, Guidant failed to disclose known potentially lethal defects to physicians, the FDA, and the public. Guidant routinely failed to inform customers of the risks inherent in its products and behaved as if it, and not the patient's medical care provider, could and should determine what risks patients should know about. In doing so, Guidant denied critical information to both doctors and patients, and made themselves responsible for clinical decisions that resulted in injuries and death.

60. In my opinion, if Guidant had informed physicians about the potential for their defibrillators to fail without warning we would have taken some, if not all of the following actions:

(a) Understood and appreciated the therapeutic risks, benefits and alternatives to continuing to implant knowingly defective 1861s in our patients;

(b) Discussed the therapeutic risks, benefits and alternatives (including explantation) with patients already implanted with failure prone 1861s. While some have called the short-prone 1861s premitigation, to mitigate is to lessen, whereas to this date I am aware of only one possible header shorting failure involving 1861s with enhanced header negative and positive contact insulation, i.e. postmitigation. Therefore 1861s manufactured post November 2002 were not mitigated; that is they were not somewhat less prone to header shorts, the occurrence of this type of failure appears to have been very significantly reduced. Patients who received premitigation ICDs, after postmitigation devices were already in process, were not denied a somewhat improved device, they were denied a PG that had been nearly "cured" of a fatal problem. In law, mitigate refers to making a crime or offense more excusable, and selection of this term may represent an attempt to make the ongoing sale of known defective ICDs a little more acceptable.

(c) Ensured that all patients who retained their1861 defibrillators, were seen promptly after each shock and at intervals of three months or less,

(d) Refused to implant premitigation 1861s,

(e) Explanted many premitigation 1861s.

61. Physicians rely on multiple sources of information, including medical journals, review courses, and meetings or publications from medical societies. However, with regard to malfunctions of ICDs, physicians must rely heavily on the medical device manufacturer to provide accurate, current and actionable information. Physicians use this information to select ICD models for new

implants, to determine the need for special or intensified follow-ups of patients with implanted ICDs, and to determine if the potential for malfunction justifies explanting an ICD. Manufacturers have an obligation to provide physicians with accurate and up-to-date information.

62. Guidant's policies and procedures with respect to disclosure of information to patients, physicians, and the public are documented in, for example, a memorandum from Alexandra Maughton to numerous company personnel on June 1, 2005, as a guide for responding to the New York Times article. The memorandum instructs recipients on how to respond to requests for additional information so the company can "quantify and manage" those requests. According to the memorandum, Guidant was in possession of a great deal of information about device defects and failures, including both statistical rates of occurrence and specific incidents. Thus, Guidant was well equipped to provide essential clinical information after, as well as before, the device failures became known. Yet, even after the New York Times made these failures and their fatal consequences public knowledge, the Guidant memorandum asserts an intention to keep tight control over the information, disclosing specified data while withholding other data from physicians and patients. As one example, the memorandum announces (in boldface type): "We will not be providing anything in writing to patients who have pre mitigation1861 devices. Refer them to their physicians." The focus of this document appears not to have been on mitigation of damage to patients through open disclosure and patient education, but primarily on damage control for Guidant.

63. It is evident that because physicians were not aware of critical risks associated with Guidant's products, they were not able to perform the functions consistent with a learned intermediary role. To the extent that physicians were vastly impaired in that role, Guidant breached its duty to disclose important risks and relevant alternatives to all of the involved physicians and their patients. The

result of this failure was the misleading of patients and physicians. In other words, a reasonable physician would expect that Guidant would report adverse reactions, mechanical failures, and other information bearing on risk, so that the physicians could, in turn, relay that information to their patients. A reasonable patient would likely infer from the absence of such a report, that no correctable defect was present in their implanted ICDs. Guidant failed to support physicians in educating the patients about a risk that had not been previously disclosed.

64. Optimal medical decision-making requires clear, open and accurate communication between physicians and their patients, as well as clear, open and accurate communications from allied professions, businesses and disciplines regarding procedures and materials that may be used in treatment. Trust and honesty are essential to this process. Depriving physicians or patients of the accurate information required for making informed treatment decisions, not only impairs that decision making process, but can adversely impact future decisions, by undermining trust between physicians and their patients. For example, a patient who feels misinformed by a physician may be less open to information or suggestions from that physician or other members of that medical profession in making care decisions in the future, and this may ultimately compromise that patient's ability to obtain appropriate future medical care. This is particularly relevant because many or most ICD patients are elderly and already vulnerable and/or were already anxious because of having experienced, or having been informed they were at increased risk of a life threatening cardiac arrhythmia. Informed consent is an ongoing process requiring accurate up-to-date information regarding risks, benefits and meaningful alternatives. Guidant failed to disclose the new and unanticipated threat to patients' lives, until after the flurry of public criticism. Thus many patients with defibrillators learned that there was a serious problem before a medical professional contacted them, likely further demoralizing

patients who already knew they were more vulnerable to death and injury than the majority of the populace.

65. I am concerned that the best interests of patients became secondary to the short term economic considerations of key decision makers at Guidant. Decisions were made on a statistical and corporate basis rather than an ethical basis, by individuals who were neither trained nor qualified to be making life and death decisions for other human beings with whom they had no contact or personal interest.

66. However decisions that clearly placed short term corporate and management interests ahead of the interests of trusting patients, and the best interests of Guidant's own field personnel, were also being made at the committee level as documented from page 70 of Guidant's own INDEPENDENT PANEL REPORT. "On January 11, 2005 the Product Performance Committee considered withdrawal of RENEWAL 1/2 from the market versus the following alternative to early withdrawal: "*Even if implanting pre-fix devices turns out to pose a clinical risk, by the time statistical surety is reached, most or all pre-fix devices will have been implanted, making the issue of pre-implant recall moot*"." I judge this to be totally irresponsible to all parties involved up to and including the company's shareholders. It says get the defective product implanted in unsuspecting patients by unsuspecting doctors, so there won't be anything to take back when we finally issue the recall.

67. This irresponsible committee was also busy spinning the problem to Guidant's own sales staff as again from page 70: "Even when the decision was made to stop shipping products, the Officer Escalation Group review of September 2, 2004 seems to focus on the field inventory of 1-2 months and the need to manage back-orders by moving inventory to the site in need. In it's meeting on August 30, 2004, the Product Performance Committee proposed response for its sales force was

"*backorders are due to a manufacturing process/yield issue that is being worked.*" There appeared to be a fundamental belief at CRM that notification of physicians would lead to unnecessary explantation and replacement of the ICDs that had already been implanted. There is no evidence that further discussion of this issue occurred with a panel of qualified medical experts."

68. The defects and adverse consequences of the eventually recalled ICDs were almost certainly sufficient to alter customers' understandings of the risk benefit ratio of using these devices, and thus would be expected to have altered the medical decision-making and treatment for a substantial number of patients.

69. I am in agreement with the Independent Panel's assertion on page 26 of their report that "drug and device makers must hew not only to business ethical standards; they must also attend to bioethical considerations, including those of informed consent or valid consent and patient-centeredness. As a general principle, the values of life and patient safety are and should be elevated over those of profit and fiduciary duties to shareholders." Indeed, physicians and patients have a reasonable expectation that the manufacturers of life maintaining medical devices adhere to these ethical standards and act accordingly.

70. I also concur with the Independent Panel's assertion on page 27 that there is "a need for an exceptionally nuanced consent process, both before cardiac devices are implanted, and afterward in cases in which new risks must be communicated and assessed." As the Independent Panel notes, "the standard is that consent should be viewed as a process and not an event." Thus they agree that informed consent must be ongoing as new information arises. Guidant's failure to disclose device failures "is seen as inconsistent with an appropriate ongoing informed consent process."

71. In addressing potential conflicts of interest, all ethical codes assert that the physician's first obligation is to the patient. For example from the AMA: "whenever physicians employ professional knowledge or values gained through medical training and practice, and in so doing affect individual or group patient care, they are functioning within the professional sphere of physicians, and must uphold ethical obligations". However Guidant's policies and practices made it difficult to adhere to this basic tenant.

72. Dr. Smith in his deposition underestimates and minimizes the responsibility of the implant manufacturer. He states, regarding Guidant products: "If they fail to perform their function, it is possible that you missed the opportunity to save a life." However, the ethical responsibilities of Guidant and the physicians in its employ go beyond missing an opportunity. Dr. Smith ignores the probability that direct harm will ensue from depriving patients of effective treatment, because of the known specific propensity for product failures. Thus it was the responsibility of anyone who became aware of the correctable risk, to convey that information to the medical community.

73. Guidant's stance on communications with physicians as indicated in an interview with the New York Times and in Smith's Deposition, that "Guidant elects to communicate with physicians when: our product fails to perform within previously determined parameters reported to the FDA... or when an opportunity to improve patient outcomes is evident..." may be too high a threshold for communication. It puts Guidant; rather physicians in the position of deciding what information might improve patient outcomes. Regardless their own policy was ignored, as an obvious opportunity to save the lives of some patients was squandered. One justification that Guidant and Dr. Smith appear to offer, for not communicating information regarding the risk of Guidant's defective implantable devices, such as the 1861, is the opinion that the risks of replacing their implants

were likely to exceed the risks of keeping them in place. Dr. Smith's testimony is corroborated by a document entitled, "Physician Notification," (Guidant Document CPI 8300016357), which sets arbitrary criteria for notifying physicians "of issues of clinical significance" (as opposed to notifying physicians of any change in the risk profile of the devices). This documented policy, by substituting the judgment of Guidant for the judgment of the individual physician, represents an improper intrusion into the shared decision making process between patients and their physicians. It also places Guidant into the physician's role, without the consent of the patient or the physician, and without Guidant being licensed to practice medicine or make therapeutic decisions.

74. Moreover, Guidant's description of the choices available to the physicians and patients, as limited to keeping the implants in place or taking them out, ignores the quite different risk profiles from one patient versus another, and deprives physicians and their patients of the meaningful alternative of testing a device before deciding whether or not to replace it. If a device had already failed for example, or the patient was young and healthy other than for the ventricular dysrhythmia and/or used their defibrillator frequently, the decision process would be quite different than for a patient with terminal cancer and a normally functioning defibrillator. The presentation of reasonable alternatives is a fundamental component of informed consent.

75. The argument by Dr. Smith and others, that Guidant's withholding of information was a decision motivated by beneficence, entails the substitution of Guidant's judgment for that of both physicians and patients. Because of the importance of individual self-determination, and of shared medical decision-making, rigorous procedures have been established whereby one party's medical judgment can be substituted for another's. For an interested party such as Guidant to unilaterally substitute its judgment for the judgment of patients and their

physicians is extremely troubling, as it ignores a range of long established and appropriate decision making processes.

76. To the extent that Guidant made false representations regarding testing of the polyimide insulation in the header, the question of conflict of interest becomes even more serious, and the judgment of some key Guidant personnel becomes even more suspect. The FDA never approved the use of polyimide by Guidant, in its components that would be constantly exposed to moisture. Further, Guidant was fully aware that the documented deaths and device failures, from its combination of material and manufacturing deficiencies, were almost certainly underestimated and under-reported.

77. The fact that, after finding the polyimide-related defect in the 1861 in February 2002, Guidant chose to alter its manufacturing process, but not to notify the FDA or take steps to recall the distributed, unimplanted, high risk product, is even more alarming. The fact that in-house product, with a known, specific, life threatening defect, was subsequently shipped is incomprehensible. When they began to manufacture modified devices in 2002, Guidant had a duty to inform physicians of their newly discovered potential for insulation failure in their defibrillators due to "break down under conditions of mechanical and electrical stress in humid conditions." Even the initial selection of polyimide is worrisome given prior fatal experiences.

78. The failure to communicate essential information to physicians was compounded by Guidant's failure to provide required notification to the FDA regarding changes in the manufacturing of its ICDs in April and again in November of 2002.

79. Marketing of inferior products without communicating that safer and more effective devices and products were readily available further undermines public trust. The lives of a number of unsuspecting patients and Guidant personnel have been unnecessarily, and in some cases permanently disrupted

80. I hold the above opinions to a reasonable degree of medical certainty. Signed under penalty of perjury, this 19th day of March 2007.

Geddes Frank Owen Tyers, M.D.

EXHIBIT D

Implant, Device-Related, and Explant Complications.

Table 1: Acute Complications of ICD or CRT-D System Implantation

1. *Venous Access Complications*
    a. *Secondary to Access Technique:*
        i. *Pneumothorax*
        ii. *Hemothorax*
        iii. *Other: injury to veins, arteries, thoracic duct, nerves, muscle and other tissue*
        iv. *Pseudohigh defibrillation threshold*
    b. *Secondary to sheath insertion:*
        i. *Air or foreign body embolism*
        ii. *Perforation of the heart or central artery/vein*
        iii. *Inadvertent arterial entry, transaortic implant and/or major bleeding with exsanguination*
    c. *Major surgical intervention for attempted rescue*

2. *Lead Placement Complications:*
    a. *Brady or Tachy arrhythmias*
    b. *Perforation of the heart or great vessels*
    c. *Exsanguination and/or cardiac tamponade*
    d. *Need for major surgical intervention (emergency or urgent)*
    e. *Damage to heart valve*
    f. *Damage to lung*
    g. *Damage to pericardium*
    h. *Damage to lead→future malfunction*

3. *Generator Complications:*
    a. *Improper or inadequate lead connection*
    b. *Header damage*
    c. *Pocket hematoma:*
        i. *NB. Markedly increased if patient is on oral anticoagulation*
    d. *Stimulation of inappropriate adjacent structures*

Table 2: Delayed Complications of ICD or CRT-D System Implantation

1. *Lead related:*
    a. *Intravascular thrombosis (embolization)*
    b. *Intravascular obstruction, superior venacaval syndrome*
    c. *Macro or micro-lead dislodgement*
    d. *Fibrosis at electrode-myocardial lead interface*
    e. *Infection/endocarditis due to lead infection*
    f. *Lead failure*
        i. *Insulation and/or conductor fracture*
    g. *Chronic perforation*
    h. *Pericarditis*
    i. *High pacing and/or defibrillation thresholds*
    j. *Over or under-sensing*

2. *Generator related*
    a. *Pain*
    b. *Erosion*
    c. *Infection – pocket and/or extracardiac perilead tissues*
    d. *Mobility – pendulum effect, edging*
    e. *Capstan effect with lead extraction*
    f. *Clavicular and shoulder impingement*
    g. *Migration / permanent drift from original implant location*
    h. *Premature failure*
    i. *Damage from extrinsic energy*
        i. *Radiation*
        ii. *Electrical shock*
        iii. *Magnetic energy*
    j. *Stimulation of chest wall muscles and/or other structures adjacent to the pocket*
    k. *Compression damage*

3. *Complications unique to Cardioverter Defibrillators:*
    a. *Inappropriate Shocks*
        i. *Approximately 15% per year on average*
        ii. *Psychological trauma associated with inappropriate shocks*
    b. *Failure to terminate life threatening arrhythmia*
        i. *Death*
        ii. *Severe Anoxic Brain Injury*
        iii. *Anoxic cardiomyopathy*
        iv. *Stroke*
        v. Myocardial Infarction