Industry Guidance for Uniform Reporting of Clinical Performance of Cardiac Rhythm Management Pulse Generators and Leads

1.0 Purpose and Scope
Manufacturers of implantable cardiac rhythm management pulse generators and leads publish Product Performance Reports to provide detailed information about the performance of these devices. This document sets forth the definitions and requirements for performance reporting to provide patients, physicians, and the public with an understanding of device performance and allow comparison among manufacturers. Manufacturers are expected to disclose fully their methodologies for reporting, including deviations from the methods described herein. This document applies to performance reporting for implantable pacemakers and cardioverter/defibrillators and associated cardiac leads.

2.0 References and Definitions

2.1 References

<table>
<thead>
<tr>
<th>Document</th>
<th>Title</th>
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<tbody>
<tr>
<td>ISO 5841-2:2000(E)</td>
<td>Reporting of clinical performance of populations of pulse generator or leads.</td>
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<tr>
<td>US FDA Guidance</td>
<td>Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions</td>
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2.2 Definitions

<table>
<thead>
<tr>
<th>Definition</th>
<th>Description</th>
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<tbody>
<tr>
<td>Complaint</td>
<td>Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device.</td>
</tr>
<tr>
<td>Confirmed Malfunction – Pulse Generators</td>
<td>Pulse generator performance while implanted and in service resulting from characteristics outside the performance limits established by the manufacturer and confirmed by laboratory analysis. Does not include changes to pulse generator characteristics due to normal battery depletion. Does not include induced malfunctions.</td>
</tr>
<tr>
<td>Device Family</td>
<td>A specified group of device model numbers with the same indications for use and designs that differ only with respect to parameters not reasonably expected to significantly affect malfunction incidence, such as pulse generator header differences or lead length. The term device refers to either leads or pulse generators.</td>
</tr>
<tr>
<td>Implanted</td>
<td>When the surgical incisions are closed (implant pocket closed)</td>
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<tr>
<td>Implant Damage – Leads</td>
<td>Damage which occurred after opening the lead package and during an attempt to implant the lead. i.e., the implant</td>
</tr>
<tr>
<td><strong>Induced Malfunction – Pulse Generators</strong></td>
<td>Device malfunction caused by external factors (e.g., therapeutic radiation, excessive physical damage, etc.) including but not limited to hazards addressed in product labeling. Damage to a pulse generator caused by a lead malfunction will be reported as a lead malfunction.</td>
</tr>
<tr>
<td><strong>Induced Malfunction – Leads</strong></td>
<td>Lead malfunction caused by use error or other external factors (e.g., scalpel cuts, damage caused during implant, sutures applied directly to lead body, explant or after explant etc.) including applications outside of labeling recommendations or addressed in product labeling as cautions or hazards in product labeling. Damage to a lead caused by a pulse generator malfunction will be reported as a pulse generator malfunction.</td>
</tr>
<tr>
<td><strong>Lead modified – Electrically</strong></td>
<td>A lead that remains connected to a pulse generator whose function is automatically altered or manually reprogrammed (e.g., changing from bipolar to unipolar or DDD to VVI mode) in response to a problem with the mechanical or electrical integrity of the lead.</td>
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<tr>
<td><strong>Lead modified – Surgically</strong></td>
<td>Any mechanical alteration of the lead (e.g., replacing a connector or the rate sensing portion of an ICD lead) in response to a problem with the mechanical or electrical integrity of the lead. Does not include successful repositioning.</td>
</tr>
<tr>
<td><strong>Malfunction – Leads</strong></td>
<td>Leads performance while implanted and in service resulting from characteristics outside the performance limits established by the manufacturer through laboratory analysis (e.g. deterioration of conductor components, deterioration of insulation components which inappropriately expose conductive materials to body fluids, separation of joined components). Does not include induced malfunctions.</td>
</tr>
<tr>
<td><strong>Malfunction with Compromised Therapy – Pulse Generator</strong></td>
<td>The condition when a device is found to have “malfunctioned”, as defined above, in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation) while implanted and in service. Therapy is considered to have been compromised if no therapy is available or critical patient-protective pacing or defibrillation therapy is not available. Examples include (but are not limited to): sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted delivery of therapy; intermittent malfunction where therapy is compromised while in the malfunction state.</td>
</tr>
<tr>
<td><strong>Malfunction without Compromised Therapy – Pulse Generator</strong></td>
<td>The condition when a device is found to have “malfunctioned”, as defined above, in a manner that did not compromise pacing or defibrillation therapy while implanted</td>
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</table>
and in service. Therapy is not compromised as long as the critical patient-protective pacing and defibrillation therapies are available.

Changes in device setting that occur as intended by the design (for example, reversion to a designed “safe mode” or Power-On Reset (POR)) that do not result in loss of critical patient protective therapies but are the reported reasons for explant shall be categorized as a Malfunction without Compromised Therapy.

Examples include (but are not limited to): error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes battery to lose power quickly enough to cause premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; mechanical problems with connector header that do not affect therapy.

<table>
<thead>
<tr>
<th>Normal Battery Depletion</th>
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<tbody>
<tr>
<td>For pulse generators, the condition when (a) a device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or (b) a device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 75% of the expected longevity using the longevity calculation tool available at time of product introduction, calculated using the device’s actual use conditions and settings.</td>
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<tr>
<th>Other Conditions Affecting Performance – Leads</th>
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<tbody>
<tr>
<td>Non-electrical findings which do not affect clinical usage or outcomes, but may, for example, influence the length of a procedure. Anomalous findings are those occasions where lab analysis reveals a secondary finding on a returned lead. These findings are not associated with a complaint. Examples include evidence of partial insulation abrasion, no conductor exposed or other cosmetic issues. Lead may have been successfully implanted.</td>
</tr>
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<thead>
<tr>
<th>Population Sample</th>
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<tr>
<td>A group of devices that is representative of the worldwide population of implanted devices. Typically devices registered as implanted in the United States can serve as the population sample, but other groups of devices may be more appropriate when the US population may not be representative.</td>
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<tr>
<th>Post-Approval Surveillance Study</th>
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<tr>
<td>Enrollment of a non-randomized sample of patients in identified centers for the purpose of prospective, active, systematic, scientifically valid collection, analysis, and interpretation of data, or other information, collected to report on device survival probability and anticipated</td>
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</table>
adverse events.

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<tr>
<th><strong>Premature Battery Depletion</strong></th>
<th>For pulse generators, the condition when a device is returned and confirmed to have depleted the battery in a time period less than normal battery depletion.</th>
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<tbody>
<tr>
<td><strong>Product Performance Report</strong></td>
<td>A document published by a pulse generator or leads manufacturer intended to report long term clinical performance of individual products.</td>
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</table>
| **Reports of Lead Complications** | A lead performance issue where a complaint, associated with a specific clinical manifestation, is reported and where the lead is:  

- Verified by medical records to have been implanted and in-service;  
- Implanted greater than 30 days  
- Not returned, but reported to have been removed from service, modified to remedy the malfunction, or left in service based on medical judgment |

### 3.0 Reporting Device Performance

#### 3.1 General Requirements

Product Performance Reports shall conform to the requirements of International Standard ISO 5841-2:2000(E) to the extent possible. If a manufacturer finds it cannot conform to this standard, the product performance report shall clearly disclose the non-conformance.

Product Performance Reports shall include event free survival predictions derived through actuarial analysis using the method described in Annex B of International Standard ISO 5841-2:2000(E). The results shall be presented in both graphical and tabular form. The report shall include, in addition to survival statistics, either effective sample size data for each time interval, or confidence limits, or both. For each device family reported, the report shall identify the population sample used as the basis of the survival statistics.

#### 3.2 Reporting by Model

Product Performance Reports shall provide the information required by this document for each model or device family.

Information shall be included in the report for all models or group of related configurations with a population sample that has accumulated 10,000 implant-months. The survival curves shall include all intervals with a population sample of 200 or more devices. A device may be removed from the report when fewer than 500 of the total initial implants are estimated to remain in service.

Data for leads being followed through post-approval surveillance registries will be reported when sufficient enrollments and data are available for a given device family.
The report must specify the population size minimums to meet protocol defined malfunction and complication cumulative survival data for inclusion of registry data. The minimum number of devices enrolled will be more than 100 and the latest interval to be reported will have a sample size of 50 or more devices which have been followed for at least 6 months. A lead may be removed from the report when either; fewer than 500 of the total initial implants are estimated to remain in service or 20 years after the original US Market approval date.

For lead models where implant location may include either the atrium or ventricle, the manufacturer may choose to report performance by implant chamber location.

3.3 Populations Subject to an Advisory
The Product Performance Report shall include a description of all relevant advisories for which an active device population exists (as estimated by the manufacturer) at the time of report publication.

When the survival performance of a sub-population of devices subject to an advisory diverges meaningfully from the population sample, survival curves and malfunction information for the sub-population should be shown separately.

3.4 Frequency and Methods of Publication
Each manufacturer shall publish an updated performance report at least semi-annually. The data cutoff date for inclusion shall be stated in the publication. Product Performance Reports shall be publicly available on the manufacturers’ web site and available in print upon request.

3.5 Adjustment for Underreported Events
Manufacturers shall consider the need to adjust the calculated survival fraction at each interval to reduce bias due to underreporting. Manufacturer shall consider underreporting of:

- Pulse generators or leads removed from service due to malfunction
- Pulse generators or leads removed from service due to patient death
- Pulse generators or leads removed from service while in specification (such as devices lost to follow up or removed due to changes in patient condition), and
- Pulse generators removed due to normal battery depletion

The Performance Report shall discuss the techniques and rationale used to derive any correction factors. The correction factors shall be described in the Product Performance Report.

3.6 Reporting Pulse Generator Performance
This section elaborates on the reporting for pulse generators for Category C devices as described in Annex A of ISO 5841-2:2000(E).

Performance reporting of pulse generators is based on laboratory analysis of returned pulse generators and shall include:
• All-cause device survival curves (comprising devices exhibiting Normal Battery Depletion, Malfunction with Compromised Therapy and Malfunction without Compromised Therapy)
• Confirmed Malfunction free survival curves (comprising devices exhibiting Malfunction with Compromised Therapy and Malfunction without Compromised Therapy).

The number of devices classified as exhibiting Normal Battery Depletion, Malfunction with Compromised Therapy and Malfunction without Compromised Therapy shall be presented in tabular form.

Survival probability for pulse generators is based on returned product analysis. Since pulse generators are designed with a finite service life, their removal and return are a normal aspect of their use. While underreporting may occur, removal and returns of pulse generators are quite typical and the percentage of PGs removed from service and returned can more easily be measured through the registration of successor device. Recognizing that these reports are also underreported and may represent a data bias, however, some method of adjustment is required and alternate methods are also permitted. Use of returned product for determination of cumulative survival excludes any device with a performance issue that does not require removal and replacement.

Note: Product Performance Reports shall define how the predicted longevity and the predicted longevity tolerance are determined. These should include descriptions of the statistical methods employed.

Note: Product Performance Reports shall define the analysis process applied to confirm a device malfunction.

3.7 Reporting Lead Performance
This section applies Annex A of ISO 5841-2:2000(E) in regard to calculating cumulative survival probability for leads. A “malfunction” occurs when, after the implant incision is closed, a lead has one or more characteristics outside the limits established by the manufacturer for clinical use, excluding induced malfunctions.

Performance reporting of cardiac leads shall include the results of Returned Product Analysis for Lead Malfunctions (described in 3.7.1), the number of Lead Complications based on complaint information, (described in 3.7.2) and Cumulative Survival Probability calculation (described in 3.7.3)

The report must specify the populations used to derive malfunction and cumulative survival data.

3.7.1 Reporting Malfunctions – Leads
Returned Product Analysis data in Product Performance Reports must include the following for each product family:
• Population description and number
• Number of leads or partial leads returned post-implant for analysis with a complaint
• Number of confirmed malfunctions, post-implant

Return Product Analysis of leads reported to have malfunctioned are included in all cause survival probability and will be reported within one of the following categories: (Only one primary lead malfunction should be reported per lead in those cases where more than one lead malfunction is identified)

a. **Conductor Fracture** – Conductor break with complete or intermittent loss of continuity that could interrupt current flow (e.g. fractured conductors). This type of malfunction includes any conductor fracture such as those associated with clavicle flex-fatigue or crush damage.

b. **Insulation Breach** – Any lead insulation breach. Examples include: 1) proximal abrasions associated with lead-on-lead or lead-on-PG contact in the pocket, 2) mid-lead insulation damage caused by clavicle flex-fatigue or crush, suture or suture sleeve, insulation wear in the region of vein insertion, and 3) distal region wear due to lead-on-lead (intracardiac), lead-on-heart valve or lead-on-other anatomy contact.

c. **Crimps, Welds and Bonds** - Any interruption in the conductor or lead body associated with a point of connection. Typically demonstrated by high or low shocking/pacing impedance, undersensing or oversensing.

d. **Other** - Includes specific proprietary lead mechanical attributes, such as lead incorporated sensors, connectors, seal rings or the IS-4 connector.

e. **Extrinsic** - Lead complication where the identified lead was removed from service and returned for analysis, where analysis was inconclusive because; only portions of the lead were available or the returned lead was damaged by the explantation process or where lab analysis could not determine an out of specification condition (including complaints of malfunction or complications such as dislodgements, perforations or failures to capture). For this particular category, malfunctions will only be included in survival probability for leads implanted greater than 30 days.

### 3.7.2 Reporting Lead Complications based on complaint information

Performance reporting shall include the number of lead complications when these data are included in cumulative survival probability calculations. A lead complication is said to have occurred when:

- At least one of the clinical observations in Table 1 has been reported, and
- The observation occurred at least 30 days after implant, and
- The lead
  - Was modified either electrically or surgically to remedy the situation
  - Was left in use based on medical judgment despite known clinical performance issue. For example, at a PG change out, if an atrial lead has low impedance and only a marginal safety margin for capture at an output level not causing pocket stimulation, such a lead may be left in place in a dual chamber pacing mode if the patient’s condition precludes safe replacement of the atrial lead.

The population and methods for identifying lead complications must be described in the Product Performance Report.
### Table 1 – Clinical Observations
The following categories taken from the FDA Guidance for Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adapter 510(k) Submissions describe performance attributes that affect a lead's clinical performance.

<table>
<thead>
<tr>
<th>Lead Complication</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Failure to capture</strong></td>
<td>Intermittent or complete failure to achieve cardiac stimulation (atrial or ventricular) at programmed output delivered outside of the cardiac refractory period. Sudden and significant increase in the pacing threshold value (elevated thresholds compared to previous measured value) at which 2:1 safety margin can no longer be achieved.</td>
</tr>
<tr>
<td><strong>Failure to sense</strong> (undersensing)</td>
<td>Intermittent or complete loss of sensing or failure to detect intended intrinsic cardiac signals (atrial or ventricular) during non-refractory periods at programmed sensitivity settings</td>
</tr>
<tr>
<td><strong>Oversensing</strong></td>
<td>Misinterpretation of cardiac or non-cardiac events as cardiac depolarization, (e.g. T-waves, skeletal muscle potentials, and extra cardiac electromagnetic interference (EMI))</td>
</tr>
<tr>
<td><strong>Abnormal pacing impedance</strong></td>
<td>Pacing impedance is typically considered abnormal if a measurement is $&lt; 200 \text{ } \Omega$ or $&gt; 3000 \text{ } \Omega$. (based on lead model and measurement range of the device)</td>
</tr>
<tr>
<td><strong>Abnormal defibrillation impedance</strong></td>
<td>Defibrillation impedance is typically considered abnormal if a measurement is $&lt; 20 \text{ } \Omega$ or $&gt; 200 \text{ } \Omega$. (based on lead model and measurement range of the device) Including high or low shock impedance when attempting to deliver a shock</td>
</tr>
<tr>
<td><strong>Insulation breach</strong></td>
<td>A disruption or break in lead insulation observed visually, electrically, or radiographically.</td>
</tr>
<tr>
<td><strong>Conductor fracture</strong></td>
<td>A mechanical break within the lead conductor (includes connectors, coils and/or electrodes) observed visually, electrically, or radiographically.</td>
</tr>
<tr>
<td><strong>Lead dislodgement</strong></td>
<td>Radiographic, electrical or electrocardiographic evidence of electrode displacement from the original implant site or electrode displacement that adversely affects pacing and/or lead performance.</td>
</tr>
<tr>
<td><strong>Extracardiac stimulation</strong></td>
<td>Clinical observation of inadvertent nerve/muscle stimulation other than cardiac muscle.</td>
</tr>
<tr>
<td><strong>Cardiac perforation</strong></td>
<td>Penetration of the lead tip through the myocardium, clinically suspected and confirmed by chest x-ray, fluoroscopy, echocardiogram, or visual observation, which results in clinical symptoms, typically degradation of pacing/ICD lead electrical performance (high thresholds), chest pain, and tamponade.</td>
</tr>
</tbody>
</table>
Specific proprietary attributes of a lead such as sensors which affect a lead’s ability to perform as designed or remain in service.

Lead performance in the first 30 days post-implant (acute) may be subject to a number of factors, including patient-specific anatomy, clinical conditions and/or varying implant conditions/techniques. Therefore, acute lead observations (those occurring within the first 30-days post implant) will be reported separately in performance reports as Acute Lead Observations. Those observations may or may not be attributable directly to lead design. Acute Lead Observations are not included in lead survival probability.

### 3.7.3 Reporting Cumulative Survival Probability

This section elaborates on reporting cumulative survival for leads as described in Annex B of ISO 5841-2:2000(E). Two alternative methods are given: a method based on data collected using a prospective clinical study and a method based on data collected using returned product analysis and complaint data. These two methods should not be construed as equivalent; it is unlikely these two methods will yield universally comparable results.

The preferred method for clinical performance reporting of cardiac leads is by use of a post approval surveillance study with sufficient enrollments to represent the entire population. Data collection using a post approval study requires procedures to verify all data relating to the clinical performance of the cardiac leads for the period being reported. These procedures may include determination of the status of cardiac leads during the relevant time period or assurances that all changes in lead status are reported as they occur.

Use of returned product analysis and complaint data from the broader field population can be used as a complement to the data from a post approval study, or as a supplement when there are an insufficient number of enrollments in the study. Data collection using returned product analysis and complaint data leads to the need to make assumptions about the status of devices for which no information has been received. Typically, the assumption is that the leads retain their last known status. Such assumptions are not always correct and may bias lead performance conclusions.

An overview of the Complication/Adverse Event categories and Return Product Analysis malfunction categorization is included in diagram 1. Diagram 1 also describes which events are included in survival probability reporting as well as what malfunctions are not included in lead survival performance data.

**Note:** Leads will not be considered for inclusion in lead survival probability calculations in those cases where the lead implant was attempted (implant damage), lead damage was induced, extrinsic factors were acute or there were findings that were non-electrical in nature.
3.7.3.1 Survival Probability using data from a post approval surveillance study

Study design must include provisions to ensure meaningful data are collected for survival reporting. These provisions include:

- Sufficient number of enrolled subjects to support survival probability calculation
- Sufficient diversity among participating centers to reduce bias due to center selection and to promote a sample representative of the total population
- Procedures to ensure all active leads are regularly followed by the study center
- Evaluation of center compliance with study protocol through regular clinical monitoring at each study site
- Procedures designed to promote consistent adjudication of events over long periods of time (years)

The report shall include a description of the study methods and statistical methods used. The following shall also be included with the survival probability data:

- Number of leads enrolled in the study as of the date of the report
- Number of leads active in the study as of the data cutoff date of the report
- Cumulative months of follow-up accrued
- Qualifying complications observed and the number of each type of complication
- Effective sample size at the annual intervals

A study based reportable event or lead complication is said to have occurred when:

- at least one of the clinical observations described in Table 1 has been reported (in accordance with the study protocol) or a returned lead malfunction was confirmed, and
- the lead:
  - was modified either electrically or surgically to remedy the situation, or
  - was left in use based on medical judgment despite a known clinical performance issue

While post approval surveillance studies represent a well controlled and prospective surveillance method, there are limitations related to measuring lead performance which are to be included in the methodologies descriptions of performance reports. For example, such studies may not identify the mechanism or root cause of the complication reported. This may lead to over-reporting or misclassification of certain complications due to lead malfunction vs. physiologic changes related or unrelated to the lead condition. Enrollment rates at the study centers may not be commensurate with of the rate of implantation across the general population and may not fully represent the general population.

3.7.3.2 Survival Probability using returned product analysis and complaint information

Survival probability using returned product analysis and complaint information shall include both lead malfunctions identified by analysis and reported lead complications.
Devices enrolled in post approval surveillance study will not be included in Return Product and Reports of Lead Complication survival analysis.

Returned product analysis is a fundamental element of a manufacturer’s post market surveillance program. It is a rich source of information about product performance and is valuable for gaining insight into lead malfunction mechanisms across a broad population of devices, implanters and centers. However, compared to pulse generators, a smaller percentage of leads are returned to the manufacturer for analysis, so lead returns data alone are limited in their use for calculating survival probability.

Reporting lead complications based on complaint information provides additional insight beyond returned product analysis malfunctions into lead clinical performance. Just as not all leads are explanted and returned for analysis, not all lead complications are reported to manufacturers. The criteria used to determine lead complications based on complaint data do not enable a lead malfunction to be conclusively differentiated from other clinical events such as an undetected lead dislodgement or exit block.

Lead complications (as defined in 3.7.2) should be used in conjunction with returned leads malfunction analysis as an adjustment to better represent survival probability in a broader population than either method would independently. The suitability of this method of adjustment may be validated by some method. The validation process may result in additional adjustment factors to more adequately correct for under reporting. In the determination of any adjustment, consideration must be made for the possibility that underreporting can change over time and may differ by cardiac lead type.

Cardiac lead survival probabilities have been partially adjusted for underreporting by including reported cardiac lead complications. However, this does not fully address underreporting because lead complications are themselves underreported, and the degree of underreporting is unknown. The topic of performance reporting based on return product analysis, complaint reporting, underreporting and adjustments should be addressed in the report methodologies descriptions and the limitations clearly described.

Diagram 1
AdvaMed Proposal for CRM Leads Performance Reporting
Reporting and Categorization Overview

**Lead Complaints**
- Lead not returned

**Lead Return Product Analysis**
- Lead malfunction
- Incl. in survival probability
- > 30 days post-implant
- Lead taken out of service
- Regardless of implant time

**Reports of Lead Complications**
- Incl. in survival probability
- > 30 days post-implant
- Lead taken out of service
- 10 Complication categories (summed)
- 10 Adverse Event descriptions (detailed)

**Acute Lead Observations (U.S.)**
- Not incl. in survival probability
- < 30 days post-implant
- Observations post implant
- Cardiac perforation
- Conductor fracture
- Lead dislodgement
- Failure to capture
- Oversensing
- Failure to sense
- Insulation breach
- Abnormal pacing impedance
- Abnormal defibrillation impedance
- Extracardiac stimulation

**Not Lead Related**
- Not incl. in survival probability
- While Implanted
- Not reported
- Induced
- Scalpel cuts, No suture sleeve (use error), Twiddler syndrome, Infection, Pt. outgrows lead
- Other Conditions
- Affecting Performance
- Implant Damage, Non-Electrical, Secondary findings

**Extrinsic Factors**
- < 30-days
- Partial, Explant Related, Inconclusive or un-confirmed by lab analysis

**Not Lead Related**
- Not incl. in survival probability
- While Implanted
- Not reported
- Cardiac perforation
- Conductor fracture
- Lead dislodgement
- Failure to capture
- Oversensing
- Failure to sense
- Insulation breach
- Abnormal pacing impedance
- Abnormal defibrillation impedance
- Extracardiac stimulation

**Conductor Fracture**

**Insulation Breach**

**Crimps, Welds and Bonds**

**Other**

**Extrinsic Factors > 30-days**