

**CARDIAC RHYTHM MANAGEMENT**

**Product Experience Report**

**Please complete all applicable sections and enter M/SN immediately below.**

Model #:       Serial #:       Lot #:       (if applicable)

**List all other product(s) involved in the product experience in Section 8 of this form**Product Issue #:      (if known)

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| **1. Report information** | | | | | | | |
| **Worksheet completed by:** | | | | | Event Information: | | |
| Name: |  | | | | Date of Event *(dd-mm-yyyy)* | |  |
| Title: |  | | | | Date BSC Employee Informed: *(dd-mm-yyyy)* | |  |
|  | | | | | Event Occurred in Country: |  | |
| **If completed by non-Boston Scientific (BSC) employee:** | | | | | If Other, enter country: | | |
| Name: | |  | | | Is Technical Assistance Needed? Y  N  Note: If yes, submit this report to [CRMEvent@bsci.com](mailto:CRMEvent@bsci.com) *and* [IntlTechservice@bsci.com](mailto:IntlTechservice@bsci.com) (for Europe, Africa and Asia Pacific) *or* [Tech.Services@bsci.com](mailto:Tech.Services@bsci.com) (for North and South America). | | |
| Company: | |  | | |  | | |
| Address: | |  | | | ***Note: All information on this form is required. If specific information is unable to be obtained it must be documented in each section.*** | | |
| City: | |  | Country: |  |  | | |

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| **2. pATIENT INFORMATION** | | | **3. PHYSICIAN/Source of information** | | |
| Patient Name or Initials (first, last): | |  | Physician/Source of Information Name:       Title: | | |
| Patient Number: |  | | Hospital: |  | |
| Patient Gender: | or  unable to obtain | | Address: |  | |
| Patient Date of Birth: *(dd/mm/yyyy):*  or  unable to obtain | | | City: |  | Postal Code: |
| Patient Weight (at time of event):      lbs      kg or  unable to obtain | | | Country: |  | |

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| **4.** **PATIENT STATUS** | | | | | | | | | | | | | | | | |
| Pacemaker Dependent | | | | | | | | | | | | | | | | |
|  | No adverse patient effects | |  | | Patient discharged to home, normal follow ups | | | | | | | | | | | |
|  | Adverse patient effects *(Please explain in section 9)* | | | | | | |  | | Patient hospitalized *(Please explain in section 9)* | | | | | | |
|  | Medical reasons (Patient related condition/not product related) *(Please explain in section 9)* | | | | | | | | | | | | | | | |
|  | Death | Date *(dd-month-yyyy):* | |  | | Time: | | |  | | | | | | | |
| Cause: | |  | | | | | | | | | |  | Witnessed | |  | Unwitnessed |
| Is it suspected that the death was related to a BSC  product malfunction? *(Please explain in section 9)* | | | | | | |  | | Unknown | |  | Yes | | No | |  |

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| **5.** **REASONS FOR PRODUCT EXPERIENCE REPORT**  **Check all boxes that apply (*at least one of the first two boxes must* *be checked).*** | | 1. **return Information**   check all boxes that apply: | |
|  | No Allegation against BSC product | Device being returned? | Yes  No product return  If yes, how many working days are needed for the return? |
|  | Allegation of Malfunction *(Please explain in section 9)* | Analysis report requested? | Yes  No |
|  | Occurred during pre-implant testing | Name of physician requesting report | |
|  | Occurred during the implant procedure prior to wound closure | Warranty requested? | Yes  No |
|  | Occurred after pocket closure (active implant) |
|  | Occurred during explant/post-explant |
|  | Occurred during routine follow up | *Warranty check box above used for affiliate*  *tracking purposes only. Every returned product is*  *assessed for warranty eligibility.* | |
|  | Advisory/Recall (prophylactic explant due only to the advisory) |
|  | Other *(Please explain in section 9)* |

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| **7. Clinical Observations (Check all that apply)** | | | | | |
| Pulse generator/Programmer | | Leads/Delivery system (Please indicate lead position, i.e. RA, RV, LV, if box checked) | | Clinical (Please indicate lead position, i.e. RA, RV, LV, if box checked) | |
|  | Fault codes/error messages  (Indicate FC number or error  message in Section 9) |  | Lead conductor fracture |  | Perforation |
|  | Beeping tones |  | Insulation issue |  | Dissection |
|  | Telemetry Problem |  | Lead dislodgement |  | Abnormal impedance measurements        Ohms |
|  | Unable to establish telemetry |  | Abnormal impedance measurements       Ohms |  | Diaphragmatic stimulation |
|  | Normal ERI, no allegation |  | Inappropriate shock |  | Resolved with reprogramming |
|  | Allegation of premature battery depletion |  | High pacing thresholds |  | Muscle/pocket stimulation |
|  | Undersensing |  | Pacing inhibition  Seconds of asystole: |  | Infection |
|  | Oversensing |  | Noise |  | Syncope, loss of consciousness  Origin *(Please explain in section 9)* |
|  | Pacing inhibition  Seconds of asystole: |  | Loss of capture |  | Migration |
|  | Unable to interrogate |  | Non-conversion of ventricular tachycardia  or ventricular fibrillation |  | Erosion |
|  | Safety Mode |  | Other (Please explain in section 9) |  | Rhythm acceleration |
|  | High defibrillation thresholds |  |  |  | Other (Please explain in section 9) |
|  | Brady pacing not delivered |  |  |  |  |
|  | Tachy pacing not delivered |  |  |  |  |
|  | Other (Please explain in section 9) |  |  |  |  |

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| **8. DEVICE/Lead STATUS** | | | | | | | | | | | |
| **List all product(s) involved in the product experience.** | | | | | | | | | | | |
|  | | **Model** | Serial # | Implant Date *(dd-mm-yyyy)* | | | | | | | |
| **Pulse Generator:** | |  |  |  | | | | | | | |
| **Lead 1:** | |  |  |  | | Lead Position: | | RA | RV | LV | Unknown |
| **Lead 2:** | |  |  |  | | Lead Position: | | RA | RV | LV | Unknown |
| **Lead 3:** | |  |  |  | | Lead Position: | | RA | RV | LV | Unknown |
| **Accessory** | |  |  |  | | **Lot# (if applicable):** | | | | | |
|  | |  | | | | | | | | | |
| Explant Date | | *(dd-mm-yyyy)* | | | | | | | | | |
|  | | | | | | | | | | | |
| Remains in Service | | | | | Removed from Service | | | | | | |
|  | No Change | | | |  | | Capped/Abandoned | | | | |
|  | Reprogrammed | | | |  | | Return to BSC | | | | |
|  | Repositioned | | | |  | | STAT analysis requested | | | | |
|  | Repaired | | | |  | | Device/lead will not be returned | | | | |
|  | Deactivated | | | | | | | | | | |
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| **Replacement Products** *(Replacement M/SN required for Warranty Credit)* | | | | | | | | | | | |
| **Model #** | | **SN#** | **Implant Date** | | | | | | | | |
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| **9.** **Product Experience Details/Clinical observations (describe the event in detail including the reported clinical observations, where/when event occurred, troubleshooting results, device/lead measurements, adverse patient effects, and patient outcome).** |
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| 10. Customer comment/enhancement request details |
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**This form will only be sent if you are connected to the BSC network. If the Send Report feature does not work, please manually attach the form to an e-mail and send to your local compliant handling contact and CRM Event Analysis (crmevent@bsci.com).**

