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|  | | | |  | |  | | |  | | |  | | |  | | | |
| **NONE** | | | |
| **Adverse Events (AEs)** | | | | **Onset** | | **Resolution** | | | **Severity**  (Select One) | | | **Action Taken**  (Select One) | | | | **Outcome**  (Select One) | | | |
| Date  (DD/MMM/YY) | | Date  (DD/MMM/YY) | | | M = Mild  D = Moderate  S = Severe | | | None  Medication Prescribed (enter on Con-Med)  Discontinued Study | | | | □ Fatal  □ Not Recovered/Not Resolved  □ Recovered/Resolved  □ Recovered/Resolved with Sequelae  □ Recovered/Resolved  □ Unknown | | | |
|  | |  | | |
| **1.**  In the tx area □Yes or □ No  Serious Adverse Event (SAE)? Yes No  If yes, \_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |  | |  | | |  | | |  | | | |  | | | |
|  | |  | | | Relationship to Device □ Not Related □  Probably Not related □ Possibly Related □  Related □ | | | | Relationship to Procedure □ Not Related □  Probably Not related □Possibly Related □  Related □ | | | |
|  | |  |  | |  | | |  | |  | | | |  | | |  | | | |  |
| **2.**  In the tx area □Yes or □ No  Serious Adverse Event (SAE)? Yes  No  If yes, \_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |  | |  | | |  | | |  | | | |  | | | |  | |
|  | |  | | | Relationship to Device □ Not Related □  Probably Not related □ Possibly Related □  Related □ | | | | Relationship to Procedure □ Not Related □  Probably Not related □Possibly Related □  Related □ | | | |
|  |  | |  | |  | |  | | | |  | |  | | | | |  | | |  |
| **3.**  In the tx area □Yes or □ No  Serious Adverse Event (SAE)? Yes  No  If yes, \_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |  | |  | | |  | | |  | | | |  | | | |  | |
|  | |  | | | Relationship to Device □ Not Related □  Probably Not related □ Possibly Related □  Related □ | | | | Relationship to Procedure □ Not Related □  Probably Not related □Possibly Related □  Related □ | | | |
|  |  | |  | |  | |  | | | |  | |  | | | | |  | | |  |
| **4.**  In the tx area □Yes or □ No  Serious Adverse Event (SAE)? Yes  No  If yes, \_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |  | |  | | |  | | |  | | | |  | | | |  | |
|  | |  | | | Relationship to Device □ Not Related □  Probably Not related □ Possibly Related □  Related □ | | | | Relationship to Procedure □ Not Related □  Probably Not related □Possibly Related □  Related □ | | | |
|  |  | |  | |  | |  | | | |  | |  | | | | |  | | |  |