|  |
| --- |
|  |
|  |  |  |  |  |  |
| **[ ]  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 = MildD = ModerateS = Severe | NoneMedication Prescribed enter on Con-MedDiscontinued Study | □ Fatal□ Not Recovered/Not Resolved□ Recovered/Resolved□ Recovered/Resolved with Sequelae□ 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 □ |
|  |  |  |  |  |  |  |  |  |