|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ADVERSE EVENT FORM | | | | | | |
| Participant ID: \_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_ ---- \_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_ | | | | Device No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| Date of enrollment: \_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (DD/MM/YYYY) | | | | Study Nurse’s Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **At the end of the study only: Check this box if the participant had no adverse events  None** | | | | | | |
| Description of Adverse Event: | | | | | Start Date: | End Date: |
|  | | | | |  |  |
| Severity | Related to the study device? | Expected (Yes/No)? | Action Taken | | Outcome | |
| Mild  Moderate  Severe  Life-threatening  Death | Definitely not related  Probably not related  Possibly related  Potentially related  Definitely related |  | None  Medical Intervention  Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Hospitalization  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Resolved  Recovered with minor sequelae  Recovered with major sequelae  Ongoing/Continuing Treatment  Condition Worsening  Death  Unknown | |
| Additional Information: | | | | | | |