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| --- | --- | --- |
| Date of complaint : | Click here to enter a date | Reserved for Evolutis |
| Customer :  |  | *File number :* |
| Healtcare institution : |  |  |
| Device reference : |  |
| Batch number : |  |

|  |  |
| --- | --- |
| Incident date : | Enter date |
| When did the incident occur : | [ ]  Before surgery [ ]  During surgery[ ]  After surgery |
| Incident description : |  |
| Incident circumstances :(Fall, physical activity…) |  |
| What are the consequences for the patient or other people ? |  |
| Was the operation time prolonged due to this incident ?  | [ ]  Yes, approximately how many minutes : [ ]  No |
| What immediate palliative action(s) were taken (how was the surgery finished/ delayed, set back…) |  |
| **Was the incriminated product recovered for analysis ?**[ ]  Yes, in which case please return [ ]  Device not implanted to Evolutis mentionning if : [ ]  Device removed or used on the patient [ ]  No, Device refused by the establishment |
| ***Avertissement*** | ***In case of use or implantation of the device on the patient, the return should be accompanied by a proof of decontamination / sterilisation (Do not autoclave a PE or resorbable implant)*** |
| **In case of an implanted device provide the following information :**[ ]  Operation notes concerning implantation of the incriminated device[ ]  Post operative x rays of the implantation of the incriminated device[ ]  Pre operative x rays of the revision[ ]  Operation notes of the revision- Age of the patient : - Sex of the patient : [ ] F [ ]  M- Weight of the patient : - Activity du patient : [ ]  No activity [ ]  Moderate activity [ ]  Very active- General condition of the patient : [ ] Good [ ]  Temporary incapacity [ ]  Permanent incapacity |
| Name/Signature : |  |