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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 : | |  | | |