|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | |  | | **CASE ID** |
| **SECTION 1: Intake Information** | | | | |
| **Completed By** | | **Date Completed** | | |
| **SECTION 2: Contact Information** | | | | |
| **Reporting Individual (First and Last Name)** | | **Profession** | | |
| **Medical Facility Name** | | **Telephone** | | |
| **Address (Country, City, State, Street Name and Number)** | | | | |
| **SECTION 3: Patient Information** | | | | |
| **Patient Initials/Identifier** | **Age** | **Sex** | **Select all event circumstances that apply:**  **Prior to Patient Involvement  Patient was Present on Table** | |
| **Is the patient in a clinical trial?  NO  YES  UNK If YES, provide** **clinical ID (CLP#-Site#-Patient#):** | | | | |
| **Relevant Medical History** | | | | |
| **SECTION 4: Event Information** | | | | | |
| **Date of Event (DD/MM/YYYY)** | | **Awareness Date (DD/MM/YYYY)** | | |
| **Description (Please provide event details, subsequent actions, vessels treated, microcatheter(s) used, and patient condition)** | | | | |
| **RHV used?  Flush used?** If yes, specify use of flush (continuous or intermittent): | | | | |
| **Did the hospital notify the FDA or any other regulatory authority?  NO  Unknown  YES** If YES, complete the following: | | | | |
| **Name of Agency** | | **Date Notified** | | |
| **SECTION 5: Product Information** | | | | | |
| **Name(s)** | | | | |
| **Catalog Number(s)** | | **Lot Number(s) / Serial Number(s)** | | |
| **Is the product available for return?  YES  NO** If NO, indicate reason: | | | | |
| **Capital Equipment?** If YES, was it found during service or maintenance?  **YES  NO** | | | | |

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