|  |  |  |
| --- | --- | --- |
|  |  | **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** |

**EMAIL COMPLETED FORMS TO:** **incident@penumbrainc.com**