**Medical device malfunction / infection case report**

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| **1. Management information** | | | | | | | | | | | | | | | | | | | | |
| 1) Control number | Identification number | | - | | | | Registration number | | | | | | - | | | | | Known/ unknown | |  |
| Report Deadline | |  | | | Location of Event | | | | | |  | | | | | | | | |
| 2) Report Category | Classification | |  | | | Type | | | | | |  | | | Receipt number of the previous report:  ( ) | | | | | |
| 3) Date of Event |  | | | | | 4) Date of information obtained | | | | | | | | | | |  | | | |
| 5) Report date |  | | | | | 6) Next scheduled report date | | | | | | | | | | |  | | | |
| 7) Health status of patients | | |  | | | | | | | | | | | | | | | | | |
| 8) Medical device malfunction status | | |  | | | | | | | | | | | | | | | | | |
| 9) Contact person | Name | |  | | | | | | | Company | | | |  | | | | | | |
| Department | | | |  | | | | | | |
| Address | |  | | | | | | | | | | | | | | | | | |
| Tel | |  | | | | | | | | Fax | | |  | | | | | | |
| E-mail | |  | | | | | | | | | | | | | | | | | |
| **2. Patient information** | | | | | | | | | | | | | | | | | | | | |
| 1) Patient's initial |  | 2) Age | | |  | | | 3)Gender | | | |  | | | | 4) Weight | | |  | |
| 5) Outcome |  | | | | | | | | | | | | | | | | | | | |
| 6) Patient status at the time of malfunction | | | |  | | | | | | | | | | | | | | | | |
| 7) Treatment taken | | | |  | | | | | | | | | | | | | | | | |
| **3. Medical device information** | | | | | | | | | | | | | | | | | | | | |
| 1) Product name | | |  | | | | | | | | | | | | | | | | | |
| 2) Generic name | | |  | | | | | | | | | | | | | | | | | |
| 3) Detailed information of the device | | |  | | | | | | | | | | | | | | | | | |
| 4) Approval / certification number, etc. | | |  | | | | | | | | | | | | | | | | | |
| 5) Medical device classification | | |  | | | | | | | | | | | | | | | | | |
| 6) Usage Status | | | □Initial Use | | | | | | Number of times used ( times)or  (Period after use months or days  or hours) | | | | | | | | | | | |
| 7) Current status of medical devices | | | (□Disposed □Remains in body □To be retrieved  □Unretrievable ) | | | | | | | | | | | | | | | | | |
| 8) Name of devices used together | | |  | | | | | | | | | | | | | | | | | |
| 9) Remarks | | |  | | | | | | | | | | | | | | | | | |
| **4. Investigation results and actions etc.** | | | | | | | | | | | | | | | | | | | | |
| 1) Investigation results | | |  | | | | | | | | | | | | | | | | | |
| 2) Actions taken so far | | |  | | | | | | | | | | | | | | | | | |
| 3) Future actions | | |  | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | |

Dear Chairman of Pharmaceutical and Medical Device Agency,

We report the malfunctions and infections case related to medical devices.

Date :

Address:

Name :