OPHARM®

## Medical Incident Report Form

| CONCERNS MEDICAL DEVICE: | DATE OF REPORT:<br><br>REPORT NO.*: |
|---|---|

**DEVICE INFORMATION**

| | |
|---|---|
| Serial number(s) and/or batch/lot number(s): | |
| UDI code: | |
| Date of manufacture: | Expiry date: |
| Notified body identification number | |

**PATIENT AND INCIDENT INFORMATION**

| PATIENT INITIALS | AGE (at the time of the incident) | SEX | DATE OF INCIDENT | PLACE OF INCIDENT |
|---|---|---|---|---|
| | | | | |

Incident description:

Consequences for the patient:

Remedial/therapeutic actions related to patient care taken by the healthcare provider:

| Number of patients affected by the incident: | Number of devices involved in the incident: |
|---|---|

Current location/disposition of the device:

□ healthcare facility □ distributor
□ patient/user □ device was discarded
□ in transit to the manufacturer
□ manufacturer □ unknown □ other, which? .....

Person using the device at the time of the incident (select one):

□ professional user □ patient □ other

Device use (select from the list below):

□ first use □ reuse of a single-use device
□ reuse of a reusable device □ after reprocessing/refurbishment
□ problem noticed before use □ other (specify): .....

**REPORTER DETAILS**

| **FULL NAME/COMPANY NAME/Patient/User/Physician/Pharmacist/Caregiver/Healthcare provider/Distributor/Importer/Other (specify)?.....** | **CONTACT DETAILS (Phone number/address/**<br>e-mail/other ) |
|---|---|

Please send the completed form to:
info@opharm.eu