MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India

FOR MDMC/NCC USE ONLY

Type of report: Initial ☐ Follow-up ☐ | Report No. :

A. PATIENT DETAILS

1. Patient Hospital ID ----------
2. Sex: M ☐ F ☐
3. Age at time of Event or Date of Birth _____
4. Weight (Kg)_____

B. EVENT DETAILS

1. Event description-

Reason for the Event(Tick) | a) Electrical ☐ b) Mechanical ☐ c) Electronic ☐ d) Biocompatibility ☐ e) Clinical application error ☐

2. Severity of the event (Yes ☐ No ☐) if yes please specify following

☐ Death (----/-------/---------) ☐ cause congenital-anomaly ☐ Life threatening ☐ Required intervention to prevent death or impairment of body function

☐ Hospitalization/Prolonged impairment/damage ☐ Disability ☐ Other (specify).....

3. Date of event - (dd/mm/yyyy)

4. Location of the event- OPD ☐ IPD ☐ Others (Please specify).....

5. Device category: (A) Therapeutic ☐ Diagnostics ☐ Both ☐ (B) Implantable device ☐ Non Implantable device ☐

(C). Single use device ☐ Reusable device ☐ Reuse of manufacture marked single use device ☐

6. Date-

Last preventive maintenance	Last calibration

7. Location of device after the incident:

Place of use ☐ Place of reporter ☐ Place of Manufacture/vendor ☐ With patient or end user ☐

8. Is device in use after incident Yes ☐ No ☐

9. (A) Is same model device available in organisation? Yes ☐ No ☐ If yes, Quantity.....

(B) Organization - Healthcare facility ☐ Manufacturer ☐

C. MEDICAL DEVICE(S) DETAIL

Name of Medical Device (1)	Manufacturer (2)	Brand Name (3)	Model No. (4)	Serial No. (5)	Batch No./ Lot No. (6)	Catalogue No. (for instruments only)	Date of installation/ implantation/ explantation (8)	List of Accessories (9)

10. Actions taken immediately after incident

11. A Whether other medical devices were being used at same time with above device for therapeutic or diagnostic service? If yes, please specify.....

11 B. Any history of adverse event(s) from device with same serial/model/catalogue number. If yes please specify.....

D.REGULATORY DETAILS			E. REPORTER DETAILS of MvPI CENTRE
Manufacturer name: Regulator in Country of origin: Regulatory status in origin country:	Entity legally representing the Manufacture: Country:	Notified Body name in: (I) Country of Manufacturing : (II) In India:	Name and Professional Address:_____ Pin:_____ E-mail_____ Tel. No. (with STD code)_____ Designation:_____ Signature:_____ Date of this report dd/mm/yyyy
F. Causality Assessment Details	Completed ☐	In Progress ☐	Awaited ☐
Additional Information:			

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. **Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.**

National Collaborating centre-Materiovigilance Programme of India.

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) under the Department of Science & Technology, Government of India. Biomedical Technology Wing, Poojappura, Thrivananthapuram 695012,Kerala. Phone: 91- 471 – 2340411, Fax: 91- 471 -2341814, Email: head-bmtw@sctimst.ac.in.

National Coordination Centre-Materiovigilance Programme of India.

Indian Pharmacopoeia Commission (IPC), Ministry of Health and Family Welfare, Government of India, Sector-23,Rajnagar, Ghaziabad-20002, Tel.:0120-2783400, 2783401, and 2783392, FAX. 0120-2783311, Email. ipclab@vsnl.net, pvpi.ipcindia@gmail.com

Technical support and Resource Centre- Materiovigilance Programme of India.

National Health System Resource Centre (NHSRC), NIHFW campus Baba Gangnath marg, Munirka, New Delhi-110067, Phones: 011 26108982 / 83 / 84 / 92 /93, Fax: 011-26108994 Email: nhsrc.india@gmail.com.

Where to report

- **Duly filled Medical Device Adverse Event Reporting Form can be send to Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), National Collaboration Centre-Materiovigilance Programme of India), Biomedical Technology Wing, Poojappura, Thiruvananthapuram 695012,Kerala,India.**
- **Or can directly email the duly filled form to mvpi@sctimst.ac.in.**
- **Call on Helpline no. 1800 180 3024 to report Adverse event.**

Event description Details of adverse event including description of device (deficiency or malfunction), clarification of hazards associated with device and the associated risk of patient, user or person any possible risk to patient associated with previous use.

Additional Information Other relevant information related to treatment should be provided.