



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 -----	3. Age at time of Event or Date of Birth _____
2. Sex: M <input type="checkbox"/> F <input type="checkbox"/>	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:	Entity legally representing the Manufacture:	Notified Body name in:	Name and Professional Address: _____ Pin: _____ E-mail _____
Regulator in Country of origin:	Country:	(I) Country of Manufacturing :	Tel. No. (with STD code) _____
Regulatory status in origin country:		(II) In India:	Designation: _____
			Signature: _____
			Date of this report ___dd/mm/yyyy
F. Causality Assessment Details Completed <input type="checkbox"/> In Progress <input type="checkbox"/> Awaited <input type="checkbox"/>			
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, Thiruvananthapuram 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), NIHFWS 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.