श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेंद्रम, तिरुवननंतपुरम - 695 011, केरलम, भारत
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
THIRUVANANTHAPURAM - 695 011, KERALAM, INDIA
(एक राष्ट्रीय महत्व का संस्थान, विज्ञान और प्रौद्योगिकी विभाग, भारत सरकार)
(An Institution of National Importance, Department of Science and Technology, Government of India)
Phone: 91-471-2443152 **Email:** sct@sctimst.ac.in

MEDICAL IMPLANT / MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI) aligned | SCTIMST Medical Device Adverse Event Monitoring Centre (MDMC)

Who may report: clinicians, nurses, biomedical engineers, patients, manufacturers, importers and distributors. Report even if the cause is uncertain; leave unknown fields blank. **Timelines:** serious events within 15 calendar days and non-serious within 30 days of becoming aware (report death or life-threatening events at the earliest and follow up). **Confidentiality:** patient identity is held in strict confidence. Submission of this report is not an admission that medical personnel, the manufacturer or the device caused or contributed to the event.

A. REPORT ADMINISTRATION

Report ID (MDMC)	SCT-MDAE-____-_____	**Report type**	☐ Initial ☐ Follow-up (No. __) ☐ Final
Date of report	*DD/MM/YYYY*	**Date reporter became aware**	*DD/MM/YYYY*
Reporting setting	☐ SCTIMST Hospital ☐ SCTIMST BMT Wing ☐ Other facility ☐ Home / personal use		

B. PATIENT DETAILS

Patient ID (code only)		**Age at event / DOB**	Age: _____ DOB: _____
Sex	☐ M ☐ F ☐ Other ☐ Unknown	**Weight (kg) / Height (cm)**	
Indication for implant			
Relevant history	☐ Diabetes ☐ Hypertension ☐ CKD ☐ Immunosuppression ☐ Smoker ☐ Anticoagulants ☐ Metal / material allergy ☐ Prior surgery at site ☐ Other: _____		
Prior event, same lot	☐ No ☐ Yes (specify): _____		

C. SUSPECTED MEDICAL DEVICE / IMPLANT DETAILS

Device / brand name		**Device category**	☐ Therapeutic ☐ Diagnostic ☐ Assistive ☐ Preventive ☐ Imaging
Implantable?	☐ Implantable ☐ Non-implantable	**Duration class**	☐ Short (<30 d) ☐ Long (≥30 d) ☐ Permanent
Device type	☐ Cardiac valve ☐ Stent / graft ☐ Occluder ☐ Pacemaker / ICD / lead ☐ Orthopaedic ☐ Neuro (shunt / coil) ☐ Dental ☐ Oxygenator / blood bag ☐ Catheter ☐ Mesh / biomaterial ☐ Other: _____		
Notified in India?	☐ Yes ☐ No	**Risk class (MDR 2017)**	☐ A ☐ B ☐ C ☐ D
Licence no. (mfg / import)		**Catalogue / Model no.**	
Lot / Batch no.		**Serial no.**	
UDI (if available)		**Mfg date / Expiry date**	*DD/MM/YYYY* | *DD/MM/YYYY*
Software / firmware ver.		**Sterility / use**	☐ Sterile ☐ Single-use ☐ Reusable ☐ Reprocessed
SCTIMST-developed device?	☐ Yes (licensee: _____) ☐ No	**Used as per IFU?**	☐ Yes ☐ No (deviation: _____)
Manufacturer (name, address)		**Importer / distributor**	
Status abroad (if not notified)			

D. IMPLANTATION / PROCEDURE DETAILS *(implants only)*

Date of implantation	*DD/MM/YYYY*	**Procedure performed**	
Anatomical site		**Laterality**	☐ Left ☐ Right ☐ Midline ☐ NA
Setting	☐ Elective ☐ Emergency ☐ Re-do / revision	**Unit / department**	
No. of devices from this lot		**Implant card issued?**	☐ Yes ☐ No
Peri-operative issues	☐ Sizing ☐ Handling ☐ Packaging damage ☐ Sterility breach ☐ None ☐ Other: _____		

E. ADVERSE EVENT DETAILS

Date of event / near miss	*DD/MM/YYYY*	**Device still in use / in situ?**	☐ Yes ☐ No (explanted / withdrawn) ☐ NA
Type of event	☐ Adverse event ☐ Malfunction / device failure ☐ Use error ☐ Near miss ☐ Product quality (packaging / labelling)		
Seriousness	☐ Serious (tick all below) ☐ Non-serious		

Serious criteria	☐ Death (date: _____) ☐ Life-threatening ☐ Disability / permanent damage ☐ Hospitalisation / prolongation ☐ Congenital anomaly ☐ Intervention to prevent permanent impairment / damage ☐ Other important medical event		
Other devices / drugs used			
Description of event (sequence, signs, symptoms, investigations, imaging, labs, condition)			
Suspected contributing factors	☐ Design / material ☐ Manufacturing defect ☐ Packaging / sterility ☐ Labelling / IFU ☐ Surgical technique ☐ Patient factors ☐ Concomitant therapy ☐ Use error ☐ Unknown		
Device retrieved for analysis?	☐ Yes (stored at: _____) ☐ No ☐ Discarded ☐ Returned to manufacturer (date: _____)	**Attachments**	☐ Imaging ☐ Lab reports ☐ Photos ☐ None

F. MANAGEMENT AND OUTCOME

Action taken	☐ None ☐ Medical management ☐ Re-intervention ☐ Revision surgery ☐ Explantation ☐ Device replaced ☐ Device withdrawn ☐ Other: _____		
Outcome	☐ Recovered (date: _____) ☐ Recovering ☐ Not recovered ☐ Recovered with sequelae ☐ Stable ☐ Death (date: _____) ☐ Unknown		
Date of intervention	*DD/MM/YYYY*	**Extra hospital stay (days)**	
If death: device contributed?	☐ Yes ☐ Possible ☐ No ☐ Autopsy pending		

G. REPORTER'S CAUSALITY ASSESSMENT

Device-event association	☐ Not related ☐ Possible ☐ Probable ☐ Related ☐ Unassessable
Rationale	

H. REPORTER DETAILS

Name		**Designation / institution**	
Reporter type	☐ Doctor ☐ Nurse ☐ Biomed. engineer ☐ Patient / caregiver ☐ Manufacturer ☐ Importer ☐ Distributor ☐ Other	**Address**	
Mobile / telephone		**Email**	
May MDMC contact you?	☐ Yes ☐ No	**Signature and date**	

I. MANUFACTURER / AUTHORISED REPRESENTATIVE SECTION *(manufacturer to complete)*

Mfr. aware date	*DD/MM/YYYY*	**FSCA / recall initiated?**	☐ Yes (ref: _____) ☐ No
Root cause analysis			
CAPA taken			
Similar events, India	Past 3 yrs: events / supplied / %	**Similar events, global**	
Risk analysis summary			

J. FOR MDMC / MATERIOVIGILANCE CELL USE ONLY

Date received / by		**Completeness check**	☐ Complete ☐ Query raised on: _____
Validated causality	☐ Not related ☐ Possible ☐ Probable ☐ Related	**Severity grade**	☐ Mild ☐ Moderate ☐ Severe ☐ Fatal
Preventability	☐ Preventable ☐ Not preventable ☐ Unclear	**IMDRF codes (device / patient)**	
Escalated to	☐ Internal committee ☐ Manufacturer ☐ CDSCO ☐ MvPI NCC (IPC) Date: _____	**Case status**	☐ Open ☐ Under investigation ☐ Closed
Reviewer / date			