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**STANDARD OPERATING PROCEDURE (SOP) FOR REPORTING  
MEDICAL DEVICE ADVERSE EFFECTS UNDER  
MATERIOVIGILANCE PROGRAM OF INDIA**

<b>Key Information</b>	
<b>Title</b>	Standard Operating Procedure (SOP) For Reporting Medical Device Adverse Effects Under Materiovigilance Program Of India at Symbiosis Medical College For Women (SMCW) & Symbiosis University Hospital And Research Centre (SUHRC)
<b>Policy Owner</b>	Medical Superintendent, SUHRC
<b>Responsible Department</b>	Head, Hospital Administration, SUHRC
<b>Approved by</b>	Dean, SMCW & SUHRC
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<b>Policy Drafter</b>	Head, Hospital Administration, SUHRC
<b>Stakeholders consulted</b>	Dean, SMCW & SUHRC; Medical Superintendent, SUHRC; Faculty Members and Administrative Staff
<b>Frequency of review</b>	Every year or as and when there is a change in policy

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2. **Preamble:** Medical devices have become integral to modern healthcare. However, adverse events involving medical devices can significantly impact patient safety. To strengthen surveillance and response, the National Medical Commission (NMC), under the guidance of the Ministry of Health and Family Welfare (MoHFW), mandates the constitution of a **Medical Device related Adverse Event Committee (MDAEC)** in each medical college, which should be aligned with the **Materiovigilance Programme of India (MvPI)** under Indian Pharmacopoeia Commission (IPC). MvPI aims to collect data on medical device related adverse events systematically and scientifically analyze them to aid in regulatory decisions and recommendations on safe use of medical devices. MvPI monitors medical device-associated adverse events (MDAE), create awareness among healthcare professionals about the importance of MDAE reporting in India and to evaluate the benefit-risk ratio of medical devices. MvPI generates independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders.

3. **Purpose:** To establish a structured framework for monitoring, assessing, and preventing adverse events related to medical devices used in the institution and to ensure compliance. Following are the primary purpose:

- (a) Ensure Patient Safety
- (b) Implement Materiovigilance at the Institutional Level
- (c) Facilitate Structured Reporting to IPC
- (d) Support Post-Market Surveillance
- (e) Promote a Culture of Safety and Vigilance
- (f) Improve Clinical Outcomes and healthcare quality.

4. **Scope and Applicability:** This SOP is applicable to all medical devices used in patient Care in various clinical as well as diagnostic departments like surgery, medicine, radiology, pathology, ICU, emergency, OPDs, or wherever medical devices. The surveillance and reporting mechanisms involve all healthcare personnel including doctors, nurses, pharmacists, biomedical engineers, technicians, CSSD staff, students and other individuals involved in handling or using medical devices in Symbiosis Medical College for Women and Symbiosis University Hospital & Research Centre.

5. **Objectives:** The following process should be followed, aligning with the **Materiovigilance Programme of India (MvPI)** and regulatory expectations:

- (a) Constitution and register the MDAEC with the Indian Pharmacopoeia Commission as per NMC guidelines
- (b) Identify and investigate adverse events related to medical devices : Medical Device Adverse Events (MDAEs) are unintended incidents related to a medical device that could have or did result in harm to a patient, user, or other person. Committee should acknowledge the medical device adverse effect/incident and investigate the matter on priority by isolate the medical device, review the patient documents, interview the staff reporting the matter, assess causality & severity and document findings & root cause analysis(RCA).
- (c) **Immediate Reporting** : All suspected adverse events should be reported to the IPC within 24 -48 hours using the standardized forms available on the IPC website (<https://www.ipc.gov.in>). Details related to Device name & its type, manufacturer/company details, description of event and reporter's information needs to be submitted. Anonymity about the patient has to maintained, hence patient information should not be submitted.
- (d) To promote patient safety by preventing device-related incidents.
- (e) To train healthcare professionals on materiovigilance.
- (f) To contribute to national databases for post-market surveillance and regulation.

6. **Policy Details:** Each medical college has to Mandatorily Constitute the MDAEC as per extant guideline and to register it with the Indian Pharmacopoeia Commission (IPC) on website using this link (<https://www.ipc.gov.in/mandates/materiovigilance-programme-of-india-mvpi/enrolment>). All staff must report medical device-related adverse events in accordance with this SOP. Timely and accurate reporting to the designated Materiovigilance Officer or Hospital Nodal Officer is mandatory. Investigations will follow defined protocols and comply with national reporting systems. Monthly reporting of nil report also to be sent on monthly basis. The NMC's require public disclosure, and functional integration of MDAECs in each medical institution to enhance device-related safety surveillance under the MvPI framework.

7. **Constitution & Details of MDAEC :** As per the MvPI guidelines shall be as under:

Sr No	Name	Designation	Status in Committee
1.	Dr. Prasad Bhanap	Med. Superintendent	Chairperson
2.	Dr. Hitender Singh Batra	Dy. Dean	Member
3.	Dr. Shubhada Sharma	Head Operations	Member
4.	Dr. Ashwani Shakya	Head Hospital Administration	Member
5.	Dr. Priti Dave	Prof & HOD Medicine	Member
6.	Dr. Shraddha Yadav	Prof & HOD Pharmacology	Member & MvPI Coordinator
7.	Dr. Amol Gautam	Prof & HOD Radiology	Member
8.	Dr. Shruti Vimal	Prof & HOD Pathology	Member
9.	Dr. Pankaj Bansode	Prof & HOD Surgery	Member
10.	Dr. Kalpana Angadi	Prof & HOD Microbiology	Member
11.	Ms. Meenakshi Gizare	Head Quality	Member
12.	Dr. Santosh Jagtap	Lab Director	Member
13.	Mr. Sunil Kulkarni	Dy. Head of Biomedical Engineering	MvPI Member Secretary
14.	Mr. Vinod Jadhav	Biomedical Engineer	MvPI Dy Coordinator
15.	Ms. Jessy Bhide	Nursing Superintendent	Member
16.	Dr. Raina Banu	Clinical Pharmacist	Member

8. **Procedure:** Procedure for Handling Medical Device Adverse Events (MDAEs) are as follows:

(a) **Identification of Adverse Event :** Any **unexpected or undesirable incident** associated with the use of a medical device is an **adverse event**. It may be detected by healthcare personnel including like doctors, nurses, pharmacists, biomedical engineers, technicians, CSSD staff, students and other individuals involved in handling or using medical devices.

(b) **Documentation and Preliminary Reporting:** Collect the following important details and report the event using the **Medical Device Adverse Event Reporting Form:**

- (i) Patient details (Name not to be mentioned)
- (ii) Device name, model, manufacturer
- (iii) Description of the adverse event
- (iv) Location and time of occurrence
- (v) Any harm caused or potential risk
- (vi) Reporter's identity and department

- (c) **Internal Review by MDAEC: Investigate the adverse effect as under:**
- (i) Review medical records
  - (ii) Interview involved staff
  - (iii) Examine and isolate the device (if applicable)
  - (iv) Evaluate if the issue is due to:
    - User error
    - Device malfunction
    - Maintenance issues
    - Environmental factors
- (d) **Root Cause Analysis (RCA):** Conduct a structured RCA
- (i) Identify source of failure
  - (ii) Assess recurrence risk
  - (iii) Determine severity and preventability
- (e) **Submit/Upload the Report on** designated **IPC / NCC-MvPI** portal or via official email to **IPC / NCC-MvPI**. Official email of Medical Device related Adverse Event Committee (MDAEC) of **SMCW & SUHRC** is [mvpi@suhrc.siu.edu.in](mailto:mvpi@suhrc.siu.edu.in).
- (f) **Corrective and Preventive Actions (CAPA) :** to be taken after investigation:
- (i) Withdraw or quarantine the device
  - (ii) Provide training to staff (if user error)
  - (iii) Update SOPs to include risk mitigation strategies
- (g) **Periodic Review and Awareness Activities:** Committee should:
- (i) Conduct regular meetings
  - (ii) Audit adverse event trends
  - (iii) Educate clinicians and staff
  - (iv) Display reporting instructions at device use areas (ICUs, ORs etc.)

9. **Responsibility:** Committee shall be responsible for Surveillance and Monitoring, detecting, investigating, reporting, Root Cause Analysis and Corrective & Prevention, Institutional Coordination, Communication with IPC and CDSCO, Training and Capacity Building, Website Information Disclosure and Periodic Review and Reporting of medical device-related adverse events, and play a critical role in enhancing patient safety and regulatory compliance under the MvPI framework. Additional to the mentioned in this para following members/users are responsible for:

- (a) Healthcare Professionals & users : Identify and report AEs.
- (b) Biomedical Engineering: Inspect devices, RCA will be conducted for each reported incident. Periodic audits and assessments will ensure policy effectiveness and regulatory adherence.
- (c) Materiovigilance Nodal Officer: Coordinate reporting, oversee investigations.
- (d) Quality & Risk Management: Maintain compliance, support RCA, and staff training.

10. **Equipment/Resources Needed :** No specialized equipment required beyond hospital systems for documentation and preserved devices for analysis, however MDAEC must be equipped with digital tools, trained human resources, standardized documentation, access to technical support and logistical space to fulfill its role effectively under MvPI as mentioned below:

(a) IT and Digital Infrastructure, Basic camera or smartphone for photographing device setup or malfunction, Barcode scanner for device identification and tracking, reporting app or internal portal access, if supported by the hospital.

(b) **Investigation and Technical Assessment Tools:** Access to Biomedical Engineering Department for:

- (i) Device inspection and malfunction analysis
- (ii) Maintenance and calibration records
- (iii) Device usage logs and service history.
- (iv) Quarantine/storage space for isolating suspect devices

(c) **Reference Materials and Guidelines**

- (i) MvPI guidelines and SOPs
- (ii) Medical Devices Rules, 2017
- (iii) CDSCO safety alerts and advisories

(c) **Human Resources and Administrative Support:** To investigate the adverse effect support from HR in respect of manpower shall be required. Support from Clinical department representatives, Biomedical engineers and Nursing and quality assurance staff shall also be required to report the matter to IPC in a time bound manner:

- (i) Coordinating materiovigilance activities
- (ii) Collecting and compiling reports
- (iii) Conducting interviews and follow-ups

#### 11. **Approvals/Guidelines/Compliance/References**

- (a) National Medical Commission (NMC) Public Notice dated 13 July 2025
- (b) Materiovigilance Programme of India (MvPI) Guidelines
- (c) Medical Devices Rules 2017
- (d) Institutional Pharmacovigilance SOPs
- (e) Indian Pharmacopoeia Commission protocols

12. **Dissemination of SOP:** This SOP along with details of MDAEC, extant guideline and references shall be:

- (a) Uploaded on the institutional website under statutory committees.
- (b) Communicated to all committee members, healthcare personnel including doctors, nurses, pharmacists, biomedical engineers, technicians, CSSD staff, students and other individuals involved in handling or using medical devices through email, circulars and notice boards
- (c) Orientation and refresher programs for existing, new staff and students.
- (d) Inclusion of orientation program for new staff and student induction activities.

13. **Training and Competency:** Regular training sessions on device safety and adverse event reporting followed by Competency assessments post-training.

#### 14. **Definitions and Abbreviations:**

- (a) MDAEC: Medical Device related Adverse Event Committee
- (b) MvPI: Materiovigilance Programme of India
- (c) IPC: Indian Pharmacopoeia Commission
- (d) CDSCO: Central Drugs Standard Control Organization
- (e) Adverse Event (AE): Any undesirable experience associated with the use of a medical device.
- (f) RCA: Root Cause Analysis.
- (g) CAPA: Corrective and Preventive Action.

- (h) **NCC:** National Coordination Centre
- (i) **Medical Device:** Instrument, apparatus, appliance, implant, or reagent for diagnosis, treatment, or prevention of diseases.
15. **Review/Revision of SOP:** This SOP will be reviewed annually or following updates in national guidelines or based on internal feedback, if deemed necessary.
16. **Repeals and savings:** Supersedes any previous SOP related to medical device adverse event reporting.
17. **Annulment of Policy:** This policy shall stand annulled upon replacement with a new version approved by the Quality Committee.
18. **Retention/Archiving of policies:** All records and documents shall be archived for a minimum of 5 years or as per hospital policy. Maintain detailed logs of all reported events and investigation outcomes. Records will be kept by the Quality and Biomedical Engineering departments.
19. **Forms/Templates & Important links:**

- (a) Medical Device Adverse Event Reporting Form (attached as **Appendix**)
- (b) <https://www.ipc.gov.in>




MEDICAL\_DEVICE\_ADVERSE\_EVENT\_REPORTING\_FORM\_Version\_1.2\_1.pdf

- (c) [https://www.ipc.gov.in/image/Medical\\_Device\\_Event\\_Reporting\\_form\\_for\\_Consumers\\_or\\_Users.pdf](https://www.ipc.gov.in/image/Medical_Device_Event_Reporting_form_for_Consumers_or_Users.pdf)
20. **Key Principles of the MvPI :** Following key principles of the MvPI must be abide by all users while reporting medical device adverse effect:
- (a) **Confidentiality:** Maintain anonymity of patients and reporters.
- (b) **Timeliness:** Urgent reporting for serious events (within 24–48 hours).
- (c) **Objectivity:** Unbiased investigation and documentation.
- (d) **Coordination:** Collaborate with departments and national regulators (IPC, CDSCO).

21. **Conclusion:** Every effort shall be made to adhere to the guidelines and directives of the Materiovigilance Programme of India (MvPI) for reporting adverse effects of medical devices on patients. This will be done with the active support and collaboration of all healthcare personnel—doctors, nurses, pharmacists, biomedical engineers, technicians, CSSD staff, students, and other individuals involved in handling or using medical devices—under the guidance of the Medical Device Adverse Event Committee (MDAEC).

Place : Pune



  
28/7/25  
Col (Dr.) H. S. Batra (Retd)  
Acting Dean  
Officiating Dean  
Symbiosis Medical College for Women  
Lavale, Tal. Mulshi, Dist. Pune-412115.



## MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

### Materiovigilance Program of India (MvPI)

This form is intended to collect information on Medical Devices Adverse Event in India. The form is designed to be used by Manufacturer/Importer/ Distributor of Medical Devices and Healthcare Professionals with direct/indirect knowledge of Medical Devices Adverse Event

#### Disclaimer

Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event. Submission of a Medical Devices Adverse Event (MDAE) Report does not have any legal implication on the reporter.

**Confidentiality:** The patient/reporter's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the patient/reporter's identity in response to a request from the public.

Primary Information	
1. Date of Report :	
2. Type of Report : Initial <input type="checkbox"/> Follow up <input type="checkbox"/> Final <input type="checkbox"/> Trend <input type="checkbox"/>	
3. Report Reference No. for MDMC only : Centre Location Month - Year Case No.	
4. Report Reference No. for MAH only :	
(For Reference No. Format, Kindly Refer to Instructions)	
Reporter Details	
1. Type of Reporter : Manufacturer <input type="checkbox"/> Distributor <input type="checkbox"/> Others <input type="checkbox"/>	Importer <input type="checkbox"/> Healthcare Professional <input type="checkbox"/> Specify
2. In case, Where the Reporter is not the Manufacturer, Fill the Following Details:-	
a) Has the Reporter Informed the Incident to the Manufacturer?	Yes <input type="checkbox"/> No <input type="checkbox"/>
b) Is the Reporter also Submitting the Report on Behalf of the Manufacturer?	Yes <input type="checkbox"/> No <input type="checkbox"/>
3. Reporter Contact Information:	
a) Name :	
b) Address :	
c) Tel. /Mobile :	
d) Email :	
Medical Device Category	
Medical Device	In Vitro Diagnostics (IVD)
I. Therapeutic <input type="checkbox"/> Diagnostic <input type="checkbox"/> Therapeutic & Diagnostic <input type="checkbox"/>	I. Kits <input type="checkbox"/>
Assistive <input type="checkbox"/> Preventive <input type="checkbox"/> Imaging <input type="checkbox"/>	II. Reagents <input type="checkbox"/>
II. Implantable Device <input type="checkbox"/> Non-Implantable Device <input type="checkbox"/>	III. Calibrator <input type="checkbox"/>
III. Invasive <input type="checkbox"/> Non-Invasive <input type="checkbox"/>	IV. Control Material <input type="checkbox"/>
IV. Single Use Device <input type="checkbox"/> Reusable Device <input type="checkbox"/>	V. IVD Electronic Reader/ Analyzer <input type="checkbox"/>
Reuse of Manufacturer Marked Single Use Device <input type="checkbox"/>	VI. Others <input type="checkbox"/>
V. Sterile <input type="checkbox"/> Non Sterile <input type="checkbox"/>	
VI. Personal use / Homecare Use <input type="checkbox"/>	

(A) Medical Device Description		
Common Medical Device Name :		
Trade Name / Brand Name :		
Details	Name	Address
Manufacturer		
Importer		
Distributor		
<p>1. Device Risk Classification as per India MDR 2017 : A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/></p> <p>2. Is the device refurbished : Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p style="padding-left: 20px;">If Yes then, Refurbishment was Performed By : OEM <input type="checkbox"/> Others <input type="checkbox"/></p> <p>3. License No. (Manufacturer/Importer) :</p> <p>4. Model No. :</p> <p>5. Catalogue No. :</p> <p>6. Lot / Batch No. :</p> <p>7. Serial No. :</p> <p>8. Software Version (If Applicable) :</p> <p>9. Associated Devices / Accessories :</p> <p>10. Nomenclature Code: GMDN/UMDNS (If Applicable) :</p> <p>11. UDI No. (If Applicable) :</p> <p>12. Installation Date (If Applicable) :</p> <p>13. Expiration Date (If Applicable) :</p> <p>14. Last Preventive Maintenance Date (dd/mm/yyyy) (If Applicable) :</p> <p>15. Last Calibration Date (dd/mm/yyyy) (If Applicable) :</p> <p>16. Year of Manufacturing :</p> <p>17. How long the Device/Equipment/Machine was in Use :</p> <p>18. Availability of Device for Evaluation : Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p style="padding-left: 20px;">If no, was the Device Destroyed <input type="checkbox"/> Still in Use <input type="checkbox"/> Return to Manufacturer or Importer/Distributor <input type="checkbox"/></p> <p>19. Is the Usage of Device as per Manufacturer Claim /Instruction for Use/User Manual : Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p style="padding-left: 20px;">If no Specify Usage</p>		

**(B) Event Description**

1. Date of Event/Near Miss Incident (DD/MM/YY)

2. Type of Event:  
 Adverse Event   
 Product Problem (e.g., defects/ malfunctions)

3. For Implantable Medical Devices Only:  
 a) If Implanted, Give Date (DD/MM/YY)  
 b) If Explanted, Give Date (DD/MM/YY)

4. Location of Event:  
 Hospital  Manufacture/Distributor Premises   
 Home  Others  Specify

5. Device Operator:-  
 Healthcare Professional  Problem Noted Prior to Use   
 Patient  Others  Specify

6. Device disposition / Current Location:  
 a) Returned to Company  If yes, Date  
 b) Remains Implanted in Patient   
 c) Within the Healthcare Facility   
 d) At Patient Home   
 e) Destroyed   
 f) Others (Specify)

7. Is Device in Use After Incidence : Yes  No

8. Serious Event : Yes   
 If yes, tick the appropriate reason  
 a) Death (DD/MM/YY)   
 b) Life Threatening   
 c) Disability or Permanent Damage   
 d) Hospitalization/Prolongation of Existing Hospitalization   
 e) Congenital Anomaly   
 f) Required Intervention to Prevent / Permanent Impairment / Damage Device   
 g) Other (Imp. Medical Event)

9. Non Serious Event

10. Whether Other Medical Devices were Used at Same Time With Above Device if yes, Please Specify Name(s)/Use(s)

11. Event Outcome and Reoccurrence Information  
 a) Event Abated after use Stopped/ Reduced?  
 Yes  No  Doesn't Apply   
 b) Event Reappeared after Reintroduction  
 Yes  No  Doesn't Apply

**12. Detail Description of Event:-**

Note: Do you have any relevant diagnostics test/laboratory data/pictures/videos related to the events Yes  No   
 If yes then kindly provide them while submitting the filled application form.

**For Manufacturer/Authorized Representative Use Only**

13. Frequency of Occurrence of Similar Adverse Event in India in Past 3 Years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)
14. Frequency of Occurrence of Similar Adverse Event Globally in Past 3 Years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)

**(C) Patient Information, History & Outcome**

1. Patient Hospital ID :  
 2. Patient Initial :  
 3. Age :  
 4. Gender : Male  Female  Transgender   
 5. Weight :  
 6. Other Relevant History, including Pre-existing Medical Conditions, Treatment, Allergy

7. Patient Outcomes:  
 a) Death (DD/MM/YY)   
 b) Recovered Date (DD/MM/YY)   
 c) Not yet Recovered   
 d) Stable   
 e) Others   
 Please Specify

**(D) Healthcare Facility Information (if available)**

1. Name :  
 2. Address :  
 3. Contact Person Name at the Site of Event :  
 4. Tel. No. /Mobile No. :  
 5. Email :

**(E) Medical Device Adverse Event Assessment**

1. Immediate Action Taken:
2. Suspected Root Cause of Problem:
3. In Your Opinion, Which of the Following Best Describe the Association between Suspected Medical Device(s) and Adverse Event?
- a) Not related  b) Possible  c) Probable  d) Related

**(F) For Manufacturer / Authorized Representative / License Holder Only**

1. Investigation Needed? Yes  No
2. Investigation Action Taken with Timeline:
3. Root Cause of Problem (Applicable for follow up / final reports):
4. Corrective and Preventive action (CAPA) taken:

**Where to report?**

Duly filled Medical Device Adverse Event Reporting Form can be send to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, or email to [mvpi-ipc@gov.in](mailto:mvpi-ipc@gov.in), [shatrughav ipc@gov.in](mailto:shatrughav ipc@gov.in). Or Call on Helpline no. 1800 180 3024 to report Adverse event.

Partnering Organizations

