1.0 OBJECTIVE

1.1 To lay down a procedure for collection of Medical Device Adverse Event (MDAE) reports at Medical Device Adverse Event Monitoring Centre(s) (MDMC).

2.0 SCOPE

2.1 This document shall be applicable to concerned officials at respective MDMCs.

3.0 PROCEDURE

3.1 Identifying a focal person as Nodal officer in each clinical department in the MDMC for communicating the Medical Device Adverse Event (MDAE) identified in their respective department to the materiovigilance section of the MDMC.

3.2 Conducting sensitization program for the healthcare professionals at your centres/ peripheral healthcare settings at least once in a month – covering the aspects like, what is MDAE, where to report, what to report and how to report.

3.3 Creating a communication channel such as E-mail, whatsApp group or any other mode of communication suitable, with the Nodal officer.

3.4 Encouraging Nodal officer to collect, compile and communicate MDAEs from their respective departments in a timely manner.

3.5 Reviewing the reports for completeness and accuracy. Uploading validated MDAE reports onto the Adverse Drug Reaction Monitoring System (ADRMS) portal.

3.6 Visiting each department (e.g., Cardiology, Surgery, Radiology, etc.), and Out Patient Departments (OPDs) twice a month to collect additional or missed MDAE reports. Also, ensure regular interaction with medical and nursing staff to encourage reporting.

3.7 The Coordinators and Deputy-coordinators shall proactively engage and collaborate with the respective state and district-level health authorities to facilitate sensitization activities under the MvPI. They shall play a pivotal role in ensuring the effective dissemination of information, promotion of reporting culture, and streamlined implementation of MvPI objectives at the grassroots level through regular

communication, capacity-building initiatives, and alignment with local healthcare systems.

4.0 SAFETY AND PRECAUTIONS

4.1 Do not use any SOP if it is not signed and issued by competent personnel or the authorized signatories.

4.2 Do not use adhesive tape or whitener on SOP.

4.3 Do not share the SOP information outside the organization.

5.0 REFERENCES

In-House

6.0 ABBREVIATIONS

6.1	SOP	:	Standard Operating Procedure
6.2	MDMC	:	Medical Device Adverse Event Monitoring Centre
6.3	NCC	:	National Coordination Centre
6.4	QA	:	Quality Assurance
6.5	MDAE	:	Medical Device Adverse Event
6.6	OPD	:	Out Patient Department
6.7	ADRMS	:	Adverse Drug Reaction Monitoring System
6.8	MEC	:	Materiovigilance Expert Committee
6.9	NA	:	Not Applicable

7.0 ANNEXURE(s)

NA

REVISION LOG		
Version	**Description of Change**	**Release Date**
00	New document for posting on IPC's website	21-JULY-2025