Journal of Pharmacovigilance and Drug Safety

An Official Publication of Society of Pharmacovigilance, India.

MvPI Alerts

Medical Device Safety Alerts issued by Indian Pharmacopoeia Commission, National Coordination Centre-Materiovigilance Programme of India (MvPI) from January - July 2021

MvPI, IPC sends details of medical device safety alerts to all Medical Device Monitoring Centre (MDMC).

Following are the alerts sent during the month of January to July 2021.[1]

S. No.	Suspected device details	Event details
1.	Device name: Auto Suture Circular Stapler Manufacturer: Covidien (Medtronic)	• Mechanical malfunction/failure • Improper pin placement • Device disassembly inside the patient during use • Misfiring of the sutures
2.	Device name: Ultrasound Biopsy Needle Manufacturer: Cook Ireland Ltd	Mechanical deformation of needle during use
3.	Device name: AMS 700 Inflatable Penile Prosthesis Manufacturer: American Medical Systems	Pump failure causing difficulty in achieving cylinder inflation Other common adverse events: • Severe scrotal and penile pain during full activation of the implant • Corporal perforation • Bleeding at the site of implant • Device migration out of the position • Device and/or tissue erosion
4.	Perfluorocarbon liquid, heavy silicone oils and intraocular membranes staining dye	Suspected acute blindness
5.	Orthopaedic Drill	Suspected adverse event
6.	Cranial Perforator	Suspected adverse event

Medical Device Recall Alert:

Recalled medical device details	**Device name:** CPAP, BiPAP, Continuous and non-continuous ventilators **Manufacturer:** Philips Respironics (For more details, kindly refer to CDSCO recall alert attached)
Indication of the adverse event	Presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)
Potential patient adverse outcome	Headache, upper airway irritation, cough, chest pressure and sinus infection, nausea/vomiting Skin, eye, and respiratory tract irritation, inflammatory response, headache, asthma Adverse effects to other organs (e.g. kidneys and liver) Toxic carcinogenic affects
Action required at your end	Discontinue use of devices affected and work with your physician or durable medical equipment provider to determine the most appropriate options for continued treatment. To continue use of the device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweigh the risk identified in the recall notice (attached herewith) Register affected device on the recall website www.philips.com/src-update If affected models in recalled notice is present at your organization, kindly respond whether any action has been taken by your organization/ manufacturer/ distributor. Kindly inform us the number of medical devices affected due to recall in your hospital. If there is no affected medical device in your MDMC/AMC due to this recall, it is also mandatory to revert back via email. Closely monitor the similar adverse events associated with the similar devices at your monitoring centre and immediately report such cases to NCC-MvPI, IPC in the medical device adverse event reporting form.

Access this article online

Website: www.journalofsopi.com

DOI: 10.21276/jpds.2020.18.01.06

Quick Response code

How to cite this article: MvPI Alerts January to July 2021. Medical Device Safety Alerts issued by Indian Pharmacopoeia Commission, National Coordination Centre-Materiovigilance Programme of India (MvPI) from January - July 2021. J Pharmacovig Drug Safety. 2021;18(1):0-0.

Source of Support: Nil, **Conflict of Interest:** None

Healthcare Professionals, Patients/Consumers are advised to closely monitor the possibility of these MDAE associated with the use of the Medical Device. If such adverse event is encountered, please report to the NCC-MvPI, IPC or nearby MDMC.

Compiled by **Gufran Ali (Pharmacovigilance Associate) under the supervision of Prof. Syed Ziaur Rahman (Coordinator) & Dr. Mohammad Sarfraz (Deputy Coordinator & Biomedical Engineer), Medical device Monitoring Centre (MvPI), Department of Pharmacology, Jawaharlal Nehru Medical College & Hospital, Aligarh Muslim University Aligarh, U.P. (India)**

REFERENCE

1. https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/