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MvPI Alerts

Medical Device Safety Alerts issued by Indian Pharmacopoeia Commission, National Coordination Centre-Materiovigilance Programme of India (MvPI) from August – December 2021.

Medical device safety alerts issued by Indian Pharmacopeia Commission, National Coordination Centre-Materiovigilance program of India (MvPI) From August – December 2021.

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 - bleeding and suture line leakage
2	Device name: AMS 700 Inflatable Penile Prosthesis	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
3	Device name: Ultrasound Biopsy Needle Manufacturer: Cook Ireland Ltd	Mechanical deformation of needle during use
4	Device name: AMS 800 artificial urinary sphincter Manufacturer: American Medical Systems	Device erosion following the implantation - Other common adverse events: - Implant placement related issues - Mechanical malfunction associated with the device - Fluid leak (de-incontinence)/ recurring incontinence
5	Device name: Panbio COVID-19 Ag rapid test device Manufacturer: Abbott Vascular	False negative result
6	Device name: Antero Medial Distal Femur Locking Plate Manufacturer: Nebula Surgical Private Limited, Rajkot, Gujarat	Device break
7	Device name: Xience Xpedition Drug Eluting Stent Manufacturer: Abbott Vascular	Balloon would not deflate during use, malfunctioning of the device
8	Device name: Proglide Manufacturer: Abbott Vascular	Oozing, hematomas, prolonged hospitalization
9	Device name: Tendril STS (Pacing system analyzer) Manufacturer: ST. Jude Medical, Inc.	lead Impedance, threshold related issue, lead related issues and screw related issue during use

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Following are the alerts sent during the month of August to December 2021.[1]

Medical Device Recall Alerts:

DEVICE	Adverse event	Reason for Recall	Immediate Action To Be Taken By User
HeartWare™ HVAD System	There is an increased risk of neurological adverse events and mortality associated with the internal pump. If the internal pump stops, it may delay restarting or fail to restart.	Medtronic is stopping the distribution and sale of the Heartware HVAD System because: • There is an increased risk of neurological adverse events and mortality associated with the internal pump. • If the internal pump stops, it may delay restarting or fail to restart.	Field representatives may assist customers with the return of unused product (sold) and the timely return of the customer signed Customer Confirmation Form. • Field representatives may assist customers with the timely return of the customer signed Customer Confirmation Form. • Other associated Corrective/Preventive Actions (CAPA) established in associated • Further, the firm is deploying a permanent corrective action to address the two issues described in the recall notice.
MiniMed™ 600 Series Insulin Pumps (Model 630G Insulin Pumps/pump kit & Model 670G Insulin Pumps/pump kit)	Serious injuries and deaths have been reported with the use of MiniMed™ 600 series insulin pumps, however those adverse events may not have been directly related to the damaged clear retainer rings that are the basis for this recall. Important Note: CDSCO have not received any complaints from the market on this issue.	Medtronic is recalling the specified insulin pumps to replace any pump that has a clear retainer ring with one that has the updated black retainer ring at no charge. A replacement insulin pump will be provided even if the clear retainer ring is not damaged and regardless of the warranty status of the pump.	Medtronic provided the following updated recommendations to customers: ● Determine if you have a clear retainer ring. ○ Users can visit www.medtronicdiabetes.com/retainer-ring-serial-number-look-upExternal Link Disclaimer and enter the serial number of the pump to check to confirm that the pump has a clear retainer ring. ● Examine the retainer ring of the pump. ● If the retainer ring is loose, damaged, or missing or the reservoir does **NOT** lock into the pump: ○ Stop use of the pump and contact Medtronic for a replacement pump. If you stop using the pump, you should follow your doctor's recommendations and perform manual insulin injections. **DO NOT insert the reservoir back into your pump while connected because you could mistakenly give yourself a rapid, and possibly large, insulin bolus**. ● If the reservoir locks in place correctly and the retainer ring is not loose, damaged, or broken: ○ Continue using the pump until you receive your replacement pump. ○ Follow instructions provided by Medtronic to replace and use the pump. ▪ Check your current and new pump and retainer ring for damage every time you replace the insulin reservoir, or any time it is dropped or bumped.
MMT-500 remote controller & MMT-503 remote controller used as an optional accessary with Ambulatory Insulin Infusion Pumps.	Potential cybersecurity risks	Medtronic is recalling all remote controllers used with either the MiniMed 508 insulin pump or the MiniMed Paradigm family of insulin pumps due to potential cybersecurity risks. An unauthorized person (someone other than a patient, patient caregiver, or health care provider) could potentially record and replay the wireless communication between the remote and the MiniMed insulin pump. Using specialized equipment, an unauthorized person could instruct the pump to either over-deliver insulin to a patient, leading to low blood sugar (hypoglycemia), or stop insulin delivery, leading to high blood sugar and diabetic ketoacidosis, even death.	If you use a recalled remote controller: ● Stop using the remote controller. ● Turn off the easy bolus feature. ● Disconnect the remote controller from your insulin pump: ○ First, you must turn off the radio frequency function and delete all remote controller IDs that are programmed into your insulin pump. ○ Then, follow the instructions in the appendix attached to Medtronic's letter. The steps to disconnect the remote controller will vary by insulin pump model.

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 events is encountered, please report to the NCC- MvPI, IPC or nearby MDMC.

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REFERENCE

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