

Urgent Safety Communication

Risks of using medications delivered into the spinal fluid to treat or manage pain that are not approved for use with the implanted pumps.

Device/ Product Name:	Implanted pumps that are connected to an implanted catheter and are used to deliver prescription medicines and fluids within the body.
Manufacturer:	There is no specific manufacturer
Problem:	Saudi FDA would like alerts doctors, patients about risk of complications when certain implanted pumps are used to deliver pain medications not approved for use with the devices
Recommendation/Actions:	<ul style="list-style-type: none"> - Healthcare providers should review the implanted pump labeling to identify the medicines and medicine concentrations approved for use with the specific pump. - Patients and providers, who experience an adverse event due to an implanted pump or suspect an infusion pump is having problems, are encouraged to file a voluntary report through Saudi Vigilance

For further information, please [Click Here](#).

Healthcare Professionals should report any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406
Fax: +966 (11) 2757245

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Sincerely,
NCMDR Team