

Safety Communication

Programmable Cerebral Spinal Fluid (CSF) Shunts and Magnetic Field Interference with Implanted Hearing Devices

Device/ Product Description:	Implanted Hearing Devices
Brand Name:	Multiple Brands
Lot numbers/Serials:	N/A
Manufacturer:	Multiple Manufacturers
Problem:	<p>SFDA wants to increase awareness about potential complications in patients implanted with both programmable cerebrospinal fluid (CSF) shunt systems (Figure 1) and some hearing implants that contain magnets, such as cochlear implants, bone conduction hearing devices, or middle ear hearing devices.</p> <p>Patients implanted with programmable CSF shunt systems may have a potential risk of experiencing an unintended change in their valve setting if exposed to strong magnetic fields.</p> <p>If magnetic interactions inadvertently change the programmable CSF shunt valve settings, then over- or under-drainage of CSF may occur. Patients may experience symptoms such as altered mental status, headaches, lethargy, irritability, vomiting, changes in vision, and difficulty walking. If left untreated, symptoms could progress to include loss of consciousness, seizures, hemorrhage, or even death.</p>
Recommendation/ Actions:	<ul style="list-style-type: none"> Educate patients and caregivers about this potential risk and be sure they know when to have their programmable CSF shunt valve checked, what symptoms are associated with potential over- or under-drainage of CSF, and when to contact health care provider.

- Check the programmable CSF shunt valve setting after placement or adjustment of other devices that contain magnets to ensure that the setting has not changed. Only a trained clinician, such as a neurosurgeon, should check the shunt valve setting and adjust the setting, if necessary.
- Consider the location of placement of the programmable CSF shunt valve if the patient has other implanted devices known to contain magnets in close proximity.
- Contact the applicable device manufacturer for further information.
- You can find more information and recommendations from the original source of Safety Alert ([Here](#)).

**Devices/Products
photo:**

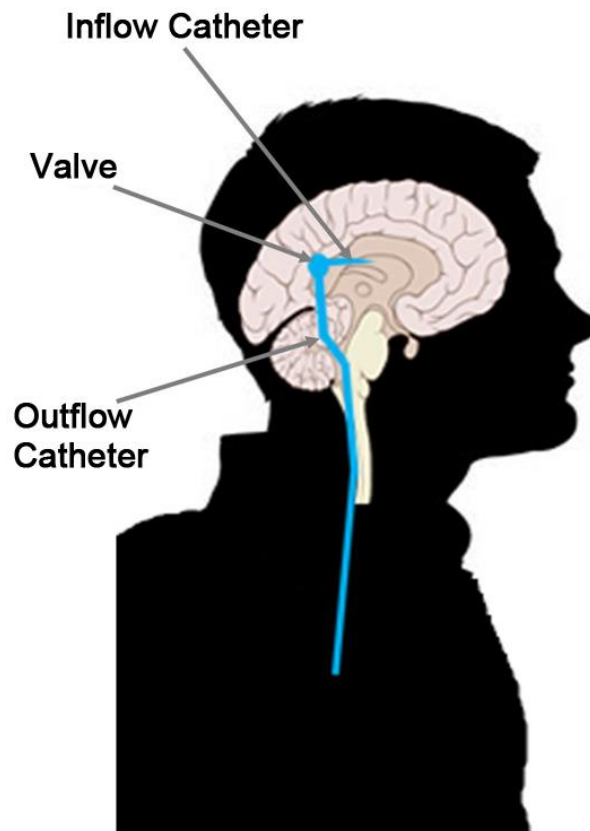


Figure 1: Side-view of implanted CSF shunt system.

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

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

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Or

Saudi Vigilance

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Sincerely,
NCMDR Team