HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Programmable Ventriculo-Peritoneal (PVP) / Programmable Cerebrospinal Fluid (CSF) Shunts

Priority 3 – Advisory

HPRA Safety Notice: SN2020(02) **Issue Date: 11 March 2020**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Various manufacturers	V40811

ISSUE

The Health Products Regulatory Authority (HPRA) would like to highlight potential complications that can arise in patients implanted with Programmable Ventriculo-peritoneal (PVP) / Programmable cerebrospinal fluid (CSF) shunts due to possible interaction with other products that contain magnets. Please see below for examples of products that could potentially cause such an interaction.

A magnetic interaction may occur when these products are located or positioned/implanted in close proximity to programmable PVP/CSF shunts. Such interactions may inadvertently activate the programmable PVP/CSF shunt valve and cause the shunt to malfunction and over/under drain. As detailed further below, unintended changes in shunt valve settings are not generally life-threatening, however there remains a risk that a life- threatening change in intra-cranial pressure could occur.

The HPRA has not received any reports of this issue occurring in Ireland.

Please refer to the U.S. Food and Drug Administration (FDA) and British Society of Audiology (BSA) publications referenced below for further details.

Examples of products that could magnetically interact with programmable PVP/CSF shunts may include (but are not limited to):

Hearing devices:

- Acoustic and Bone conduction hearing aids
- Cochlear implants
- Osseointegrated Hearing Aids

Audiology equipment:

- Supra-aural or circum-aural earphones
- Bone conductors
- Otoacoustic emissions probes
- Tympanometer probes
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In addition to the above listed products, please note that in theory any product with a sufficiently strong magnetic field could interfere with programmable PVP / CSF shunts.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Read this Safety Notice and the associated FDA communications carefully.
2. When implanting or using a device which may potentially interact with a programmable PVP/CSF shunt, identify if the patient may have a programmable PVP/CSF shunt and, if so, take any necessary steps to minimise the interaction.
3. Where a device that may potentially generate a magnetic field is identified in close proximity to a programmable PVP/CSF consider steps to minimise the interaction and to regularly monitor the programmable PVP/CSF shunt settings and function on an appropriate schedule.
4. Ensure that patients and/or care-givers understand the risk associated with this issue and the potential sources of magnetic fields.
5. Ensure that patients and/or caregivers are aware of the symptoms of over or underdrainage and the necessity to attend a healthcare professional immediately if any of these symptoms occur after the procedure.
6. Ensure that valve settings are checked regularly and ensure scheduling of routine physician checks.
7. Report any adverse incidents associated with these devices to the manufacturer and to the HPRA.

The HPRA advises audiologists:

8. Read this Safety Notice and the associated BSA and FDA communications carefully.
9. Report any adverse incidents associated with these devices to the manufacturer and to the HPRA.
10. If involved in the provision of audiology services using devices highlighted above that may contain a magnet, please consider this safety notice and consider the need to amend any pre-op/ pre-test checks lists and your consent documentation to include a referent to this risk.

TARGET GROUPS	
Audiologists Caregivers Clinical Directors Clinical Engineers Ear, nose and throat Consultants Emergency department staff Emergency responders General practitioners Hospital Managers / CEOs	Neurologists Neurosurgeons Nurses Nursing Managers Paediatricians Risk Managers Radiologists Radiographers Theatre Staff

BACKGROUND

Recent American (FDA)1,3,4 and UK (BSA)2 published safety advice have highlighted the potential for serious adverse events attributable to unintended changes in magnetic externally adjustable PVP/CSF shunt valve settings. These publications highlighted the need to raise awareness of the potential for a magnetic interaction to occur between these devices and other products when they are located or positioned in close proximity to each other and within each other's magnetic fields.

Although the potential risk relating to this issue includes a life threatening change in intra-cranial pressure, the FDA has highlighted in its publications that unintended changes in shunt valve settings are generally not life-threatening. Routine physician visits, checking and resetting of valves after MRI procedures, and understanding the symptoms associated with under and over drainage help to maximise the early detection of inadvertent activation of shunts. The FDA advised that the majority of problems associated with malfunctioning drainage are resolved before health conditions deteriorate, with headaches often being the first symptom associated with a malfunction. Other symptoms can include altered mental status, lethargy, irritability, vomiting, changes in vision, and difficulty walking. If left untreated, symptoms could progress to include loss of consciousness, seizures, haemorrhage, or even death.

It has been highlighted that young children are at higher risk of this issue as they may not be able to communicate certain symptoms, potentially delaying their medical care.

The HPRA is issuing this Safety Notice to raise awareness of this issue.

Further information:

1) The U.S. Food and Drug Administration (FDA), 2019. Magnetic Field Interference with Programmable CSF Shunts. Available at: https://www.fda.gov/medical-devices/letters-health-care-providers/programmable-csf-shunts-and-magnetic-field-interference-implanted-hearing-devices-letter-health-care

2) British Society of Audiology (BSA), 2019. Interim Safety Advice to Audiologists on Performing Hearing Tests and Fitting Hearing Aids to Patients with a Programmable Ventriculo-peritoneal Shunt (PVP Shunt) Available at:

https://www.thebsa.org.uk/interim-safety-advice-to-audiologists-on-performing-hearing-tests-and-fitting-hearing-aids-to-patients-with-a-programmable-ventriculo-peritoneal-shunt-pvp-shunt/

3) The U.S. Food and Drug Administration (FDA), 2018. Information for Patients and Caregivers about Magnetic Field Interference. Available at: https://www.fda.gov/medical-devices/cerebral-spinal-fluid-csf-shunt-systems/information-patients-and-caregivers-about-magnetic-field-interference

4) The U.S. Food and Drug Administration (FDA), 2018. Cerebral Spinal Fluid (CSF) Shunt Systems. Available at: https://www.fda.gov/medical-devices/implants-and-prosthetics/cerebral-spinal-fluid-csf-shunt-systems

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

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