

How to report an incident to the HPRA

If your medical device poses a risk to your health and safety, please report the problem to your health care provider, the HPRA and the manufacturer of the device. You should report any unexpected problem or malfunction that may affect your health or cause or contribute to an injury, for example, poor vision following a lens implant where your doctor assesses the problem could be due to the lens.

You can report incidents to the HPRA by filling in our online user report form on www.hpra.ie. If you would prefer to fill out a printed copy of the form, you can download it from our website or request a copy by phone or e-mail.

More information

This is one in a series of information leaflets that you can get from the HPRA and from our website: www.hpra.ie.

You can also get more information on the Irish Heart Foundation website: www.irishheart.ie, and the Diabetes Federation of Ireland website: www.diabetes.ie.

The Health Products Regulatory Authority (HPRA)

Our role is to protect and enhance public and animal health by regulating medicines, medical devices and other health products.

What does the HPRA do?

As the regulatory authority, we monitor the safety of all medical devices available in Ireland. Our aim is to make sure that these products do not compromise the health and safety of the patient or the person using them. We also work to ensure that medical device manufacturers comply with all safety regulations.

(The HPRA cannot provide advice on which medical devices you should buy.)



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MEDICAL DEVICES

Implantable medical devices



www.hpra.ie

OUR ADVICE ON

Implantable medical devices

An implantable medical device is one that is placed inside your body during a medical procedure, such as surgery, and is intended to stay there after the procedure.

Examples of implantable devices include cardiac pacemakers, implantable cardiac defibrillators (ICDs), coronary stents, hip implants, interocular lenses and implantable insulin pumps. Some implantable medical devices, such as a pacemaker, may be battery-powered.

General tips

- Make sure you understand what your device does and why you need it.
- Talk to your doctor about what to expect during your recovery period. Ask them when you will be fit for work, fit to drive and fit to travel.
- Ask your doctor about follow-up care and who you should contact if you have any problems in the days after your procedure, such as excessive bleeding, bruising or significant pain at the implant or wound site.
- Keep all follow-up appointments. Powered devices such as cardiac pacemakers and ICDs need to have batteries, wires and software checked regularly.

- Take all the medication your doctor prescribes. If you have artificial heart valves or some types of stent, you will need to take long-term medication to prevent blood clots. Do not stop this medication unless your doctor tells you to. If you have any side effects from your medication tell your doctor without delay.

Tips for pacemakers, ICD and implantable drug pumps

- Always carry your device ID card with your name and details of your device.
- You must tell health professionals, doctors, nurses or dentists about your device, as you may need to avoid some medical tests and treatments such as CT, MRI scans and TENS devices.
- You should tell your family and close friends that you have an ICD, a cardiac pacemaker or an implantable drug pump. Tell them what to do if you lose consciousness or collapse.
- If your device has a battery, ask your doctor how you will know when the battery needs to be replaced or recharged. Make sure you know what to do when the batteries in your device run low.
- Batteries are recharged or replaced in hospital. Know when, where and who you need to attend to have this done. You may need to replace the batteries in the remote control of some devices. Make sure you know where to get replacements.
- Some powered devices may be affected by electromagnetic interference from security systems, electricity generators and arc welding equipment. Follow your device manufacturer's safety recommendations. Make sure that electricity generators and arc welders are grounded and leave the area immediately if you feel light headed or faint.

- If you have a pacemaker or ICD, it is not safe to walk through airport security systems or to be scanned with a hand-held security wand. Show your official ID card to airport security staff. It is safe to walk through shop security systems at a normal pace, but do not sit or stand nearby.
- In general, household equipment such as microwave ovens and computers are safe to use, but always check the manufacturer's instructions.
- It is safe to use mobile phones, but hold them to the ear opposite your implant and do not carry them in your breast pocket.
- Avoid wearing magnetic bracelets and magnets near your chest.

Device details

Use this form to record the essential details about your device:

Your name:

Name or type of device:

Date of implant:

Model or serial no:

Consultant or hospital phone no:

Follow up contact person in case of problems:

Phone no:

Other notes:

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