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.)

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.

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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: __________________________