Implantable cardioverter defibrillator For informed consent

#heart HQ

Pulse Generator Change

Your doctor has recommended you undergo a pulse generator change, also known as an implantable device replacement.

You might not have heard this medical term before now and may be feeling unsure about the nature of the procedure.

This information sheet outlines what the procedure is and what preparations and risks are involved.

After you read this information sheet, you might still have questions. If you do, please contact the team at Heart HQ. We're here to help.

1. What's a pulse generator?

Your implanted device is made up of two main parts: a pulse generator and a set of leads.

The pulse generator is a small metal box which contains electric circuits and a battery. During the first placement of your heart device, your doctor put this generator under your skin or the muscles of your chest wall. Normally, these generators are powered by lithium batteries. They work for 5 to 10 years before they need to be replaced. To replace the pulse generator, you will need a pulse generator change procedure.

2. How does it work?

The procedure for replacing your pulse generator is not as complex as you may think.

The procedure starts with an intravenous line (IV) being placed into a vein in your arm. This is for the medical team to administer medication during or after your procedure. You may receive an antibiotic to prevent an infection of your new pulse generator. A sedative will also be given. You will have an injection of local anaesthetic to numb the area below your left collarbone. After, an incision is made into the pocket of skin surrounding the generator.

Your doctor then disconnects the leads from the pulse generator and removes it from the pocket. The new generator is placed in the same pocket and the leads are reconnected.

During the procedure, your doctor will be able to see the leads using x-ray imaging. An absorbable antibiotic pocket may also be used to minimize the risk of infection.

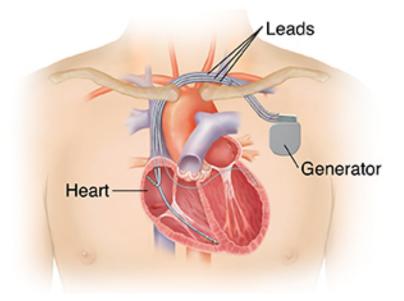
Once your doctor has reconnected the leads correctly, the new pulse generator will be tested to make sure they are working properly. The pocket and your skin will be closed using dissolving sutures and a wound dressing will be placed over the incision.

NOTE: If you are device dependent you will also have a temporary pacing wire attached during your pulse generator change.

Temporary cardiac pacing is used to maintain a normal heart rate in people whose own heart rate is not pumping enough blood around the body. This may be in slow heart rhythms, fast rhythms or when the heart fails to beat on it's own.

In temporary cardiac pacing, wires are inserted through a large vein in the groin and are directly connected to the heart. These wires are connected to an external pacing box, which delivers a current to the heart to make it beat normally.

Your Doctor will advise you pre-procedure if you require temporary pacing during your pulse generator change.



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3. What happens after the procedure?

You will not be able to drive a vehicle for two weeks after having a pulse generator change. You will also need to limit your arm movement on the side of your implant as much as possible during those first two weeks to allow the devices wires to settle.

About two weeks after your procedure, you will have an in-clinic appointment where a pacing technician will check your device and your doctor will remove the wound dressing.

You will then need follow-up appointments on a regular basis at the clinic or through our remote home monitoring service. We will check the operation of your cardiac device and review any abnormal heart rhythms stored on the device.

4. What kind of risks are associated

with this procedure?

Any kind of procedure carries some element of risk, often very small and rare.

Your doctor has balanced the benefits and risks of carrying out the test against the benefits and risks of not proceeding. If your doctor has recommended this procedure, they believe there is benefit to you going ahead.

It's important you understand the risks involved so you can make an informed decision.

Here are the most commonly reported risks and complications associated with an installation.

Uncommon risks and complications (1–5% of cases)

- Bruising and bleeding in the pocket
- Pocket infection

Rare risks and complications (less than 1% of cases)

- Blood clot in the vein or deep vein thrombosis (DVT)
- Blood clot in the lung or pulmonary embolism (PE)
- Heart attack
- Stroke
- Death from any complications

Our commitment to you

As a patient of Heart HQ, you can be assured we will always strive to act in your best interests and we will only recommend tests and procedures we believe will benefit you.

Everyone has questions, and we want to answer yours. Please contact your doctor to talk over any concerns you might have.