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Leadless Pacemaker Insertion

Leadless Pacemakers are small, computerised devices that can be surgically implanted in some patients as an alternative to a traditional pacemaker.

The devices themselves are generally around 3-5cm in length and just over 5mm in diameter that possess an internal battery capable of delivering treatment for many years depending on a patient's individual requirements. The use of leadless pacemakers allows patients to have ongoing care and treatment provided in a less surgically invasive way that allows them to continue living a generally otherwise uninterrupted life.

In general, the most common insertion reasons can include:

- Bradycardia (slow heart beating)
- Syncope (blackouts from extended periods between heart beats due to electrical conduction issues
- As an adjunct therapy for ongoing management of arrhythmias where patients are unable to tolerate medications required for treatment

The initial insertion of a leadless pacemaker requires an overnight admission for observation. Patients requiring a generator change are brought back into hospital for a second overnight admission as the removal and reinsertion process is very similar.

In recommending this procedure, your doctor has made has determined that on balance, the benefits and risks of the procedure outweigh the benefits and risks of not proceeding. As such, your doctor believes there is a net benefit to you going ahead and that the procedure should be successful overall.

What are the risks involved in a leadless pacemaker insertion?

As with all procedures, the insertion of a leadless pacemaker carries their own risk profiles that can range from common occurrences, through to uncommon and rare instances. All Risks should be taken into consideration when considering a leadless pacemaker insertion to determine if the procedure is an appropriate treatment option for yourself during consultation with your treating cardiologist.

Common risks and complications can include but are not limited to:

- Bruising to the surgical access site/puncture site and surrounding tissues that can take weeks to heal completely in some instances.

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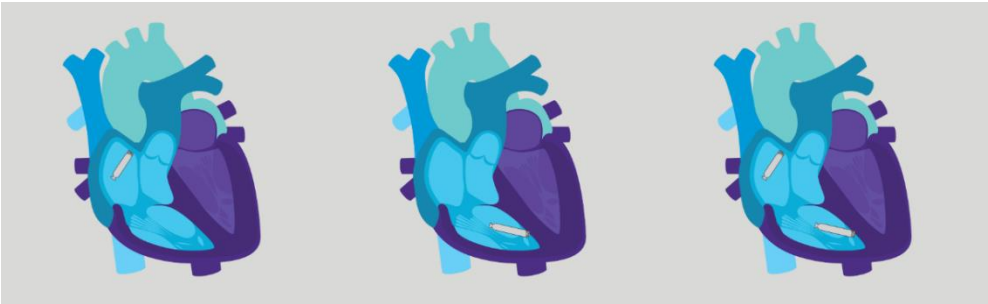
Uncommon risks and complications can include but are not limited to:

- Blood pooling around the heart (tamponade) that requires immediate drainage or surgical intervention in extreme cases.
- Persistent or considerable bleeding to the access site that can require surgical repair in some cases.
- DVT or blood clot formation.
- Internal bleeding that may require immediate surgical intervention
- Incidences of death due to this procedure are considered incredibly rare but are still possible

Leadless devices

The use of leadless pacemakers is a recent advancement in the field of pacemaker therapy. At present, devices are seperated into two groups – atrial devices and ventricular devices. Due to their smaller size, leadless devices can be implanted through the patients femoral vein rather than undergoing a surgical insertion in the patients chest wall. This allows for devices to both be implanted and removed through minimally invasive surgical procedures and offers a lower potential for infection and complications. Unlike traditionally implanted permanent pacemakers, leadless devices are not able to be connected to remote monitoring devices at present, and are programmed or interrogated in person through a process of 'blood pool' telemetry rather than the use of radiofrequency or bluetooth connections. This means that signals are sent electronicly through a patients cardiovascular system through the use of an interrogation device in clinic as opposed to a wireless bluetooth monitor interrogation device used by traditional devices either at home or in clinic.



Atrial Device Ventricular Device Dual Chamber Devices

What Can I expect during the procedure?

Once checked into hospital for your procedure, you will be taken through an admission process where a detailed medical history is taken, preprocedural blood tests are collected and your body is prepared by shaving off any hair to your groin, chest and back. This is undergone to ensure a sterile surgical field can be created to reduce any chance of infection and ensure that any defibrillation pads or monitoring electrodes can be

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appropriately placed on your chest or back in a way that is both effective for use and easy to comfortably remove.

You will then be taken to the anaesthetic holding bay where your anaesthetist will discuss their part in the procedure, (as anaesthetic is required) and discuss any queries or concerns you may have. Upon entering the cardiac catheter laboratory, you will be prepared for your procedure by the nursing staff who will position you on the table and apply defibrillation pads and various monitoring electrodes to your body prior to anaesthetic administration.

At the commencement of the procedure once you have been anaesthetised and surgically prepared by the staff assisting with the procedure, the doctor will insert an access sheath or tube into your right groin under ultrasound guidance before passing a catheter up through your femoral vein and into the right atrium or ventricle of the. This is performed under x-ray guidance. A series of x-ray contrast images are also taken to visualise the atrium or ventricle. Numerous electrical measurements are taken through the device to determine the best position to deploy the pacemaker. Once the optimal position of the device has been established, it can be 'screwed' into the cardiac muscle and appropriately tested for attachment before finally being released.

Once device has been deployed, the catheters and access sheath will be removed and a 'figure of 8' suture is inserted to the access site to apply pressure by temporarily pulling the surrounding tissues over the puncture in the femoral vein. The patient is then awoken from their anaesthetic and transferred to the post anaesthetic recovery area for observation before being transferred to their room in the coronary care for overnight observations. Once the catheters have been removed, patients generally have to remain flat without moving their hips/legs for up to 2-4 hours depending on whether they experience any bleeding postoperatively.

The entire procedure is generally reasonably quick, taking around one to two hours to complete in most cases however can take longer if optimal device positioning proves difficult to achieve and additional cardiac mapping of electrical signals is required. Provided no complications are observed post-operatively, patients are generally discharged the following day once the device settings have been rechecked by device technicians and the patient has been reviewed by their doctor.

Before Your Procedure

It is important that you fast prior to your procedure in line with your anaesthetists' instructions. Generally, a fast time of 6 hours for solid food and 2 hours for water is required in order to prevent any complications with the use of anaesthesia during your procedure.

For patients taking Ozempic, Trulicity, Saxenda, Wegovy or Mounjaro, the anaesthetic guidelines require you to continue your medication as normal, commence a clear fluid

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diet 24 hours prior to your procedure and completely fast for 6 hours immediately prior to your procedure to minimise the potential for anaesthetic related complications.

Note: Clear fluids includes: water, apple juice, broths, black coffee and black tea. Any non-transparent fluids such as milk, smoothies, juice containing pulp or soups are not considered clear fluids and can cause a delay in your procedure time if consumed.

After Discharge Process

Prior to discharge from hospital, patients are advised of any changes to their regular medications by their discharging doctor and advised of their follow up process. This usually consists of an in clinic appointment with a device technician and Dr. Hunt to assess the devices functionality 6-8 weeks following the procedure. If you are unsure if an appointment has been made, please contact the clinic to confirm a date and time for review.