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Left Atrial Appendage Occlusion Devices (Watchman)

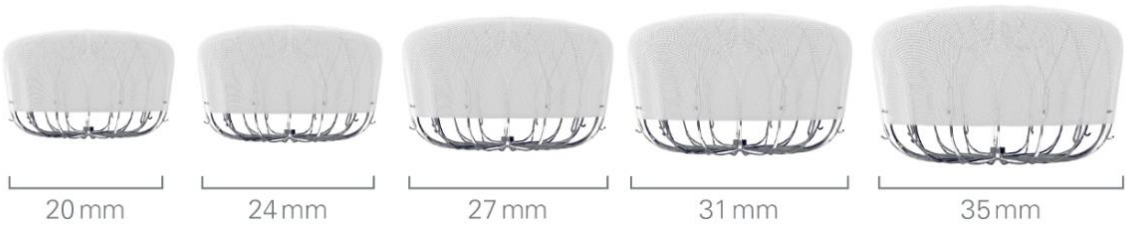
Patients experiencing atrial fibrillation (AF), are at an elevated risk of stroke. This is due to clot formation in the left atrium which can dislodge (embolize) and block an artery downstream. If the clot blocks an artery in the brain, the part of the brain supplied by that artery dies, which results in a stroke.

Some patients are unable to take anticoagulation, often because it causes either unacceptable bleeding, or they are at risk of significant bleeding. These patients are at considerable risk of stroke or thrombus related events.

In patients with AF, it is estimated that 90% of clots originate from the left atrial appendage (LAA), a small pouchlike structure that hangs off the left atrium. If the left atrial appendage is either removed or sealed off, this reduces stroke risk.

The use of left atrial appendage occlusion devices presents a minimally invasive means of reducing stroke risk by sealing the LAA completely. The devices themselves are available in a variety of sizes depending on the anatomy of the individual Once implanted, the patient will reduce anti-coagulation, often either remaining on aspirin alone long term, or in some instances, stopping anti-coagulation entirely.

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 an LAA occlusion device insertion?

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

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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.

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.
- CVA or stroke symptoms (either temporary or permanent)
- Damage to an artery in the groin that can require surgical repair in some cases.
- Injury to the oesophagus from procedural use of an endoscopic ultrasound probe
- Device dislodgement
- Incidences of death due to this procedure are considered incredibly rare but are still possible

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 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, your airway management process (as general anaesthetic is required) and discuss any queries or concerns you may have prior to the introduction of any medications. 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 electrodes to your body prior to anaesthetic administration.

At the commencement of the procedure, you will be anaesthetised and surgically prepared by the staff assisting with the procedure. The doctor will insert a series of small access sheaths or tubes into your right groin under ultrasound guidance before passing a catheter up through your femoral vein into your heart under x-ray . The doctor will then pass a long needle through the septum (wall between the left and right sides of the heart)

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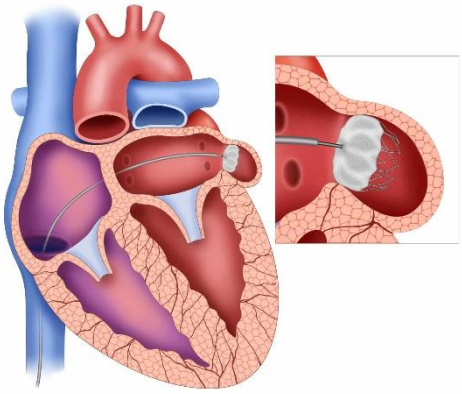
to allow for the device catheters to be advanced into the appropriate location – this puncture hole reduces in size and eventually heals up over the course of several months.



Throughout the procedure, additional blood thinners are administered to maintain a suitable level of anticoagulation of the blood and ensure the patient does not experience a stroke from clot formation following the introduction of the sheaths or device catheters. Once the catheter has been advanced into position and a series of measurements are taken with the use of transoesophageal ultrasound (TOE), the appropriately sized device is then manoeuvred into position and deployed. Once the device technicians and doctors involved in the procedure are satisfied with its location. A 'tug test' is performed prior to removing device catheters to ensure the closure device is adequately seated into position and not at risk if migrating or dislodgement.

The entire procedure is generally reasonably quick, taking around 90-120 minutes to complete. At the completion of the procedure, a temporary figure of eight suture is utilised to close the access site and prevent any bleeding. Patients are then awoken from their anaesthetic and transferred to the post anaesthetic recovery area for observation prior to transferring to their room in coronary care for overnight observation. At the completion of the procedure, patients are required to remain flat on their back without moving their hips/legs for up to 2-4 hours to minimise the potential for post procedural bleeding from the access site. Provided no complications are observed post-operatively, patients are generally discharged the following.

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 4 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 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.

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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 returning to the hospital for a transoesophageal echocardiogram procedure 6-8 weeks after the initial implant to assess the position of the LAA occlusion device, followed by an appointment with your cardiologist. If you are unsure if an appointment has been made, please contact the clinic to ensure all pre-appointment testing can be completed in a timely manner.