

Having a closure of the left atrial appendage in your heart (left atrial appendage occlusion LAAO)

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Introduction

The left atrial appendage (LAA) is a small sac in the muscle wall in the top left chamber of the heart. You may hear this procedure called a trans-catheter closure of the left atrial appendage occlusion (LAAO). It is used with patients who have heart problems called atrial flutter or atrial fibrillation (AF). The aim is to reduce the risk of stroke.

This leaflet will help you understand what to expect before, during, and after the procedure. If you have any questions that the leaflet does not answer, there are helpful contact numbers listed at the end.

What is atrial fibrillation (AF)?

AF is the most common irregular heart rhythm. It occurs in 1 in 100 people. It happens most often with age. It is very unusual under the age of 30. It affects 1 in 20 people over the age of 65.

The heart has 4 chambers:

- 2 collecting upper chambers,
- 2 pumping lower chambers.

When the heart beats normally, its muscular walls tighten and squeeze (contract) to force blood out and around the body. They then relax so the heart can fill with blood again. This process is repeated every time the heart beats.

In atrial fibrillation, the heart's upper chambers (atria) contract randomly and sometimes so fast that the heart muscle cannot relax properly between contractions. This reduces the heart's efficiency and performance. This can result in clots forming in the left atrial appendage (LAA). The clots can then travel to other parts of the body, causing problems such as a stroke.

Health information and support is available at www.nhs.uk or call 111 for non-emergency medical advice

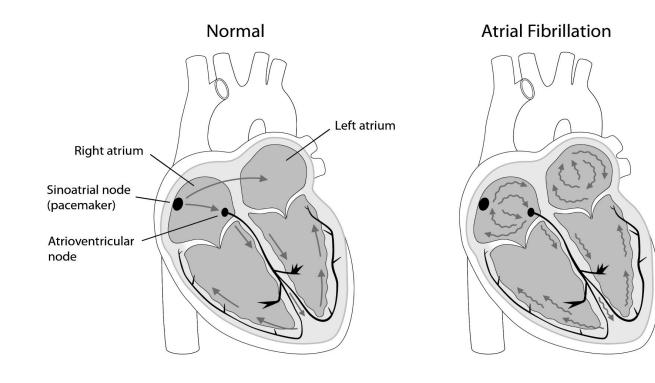
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AF often does not cause any symptoms in some people, but others may have uncomfortable symptoms such as

- palpitations
- tiredness (fatigue) and less able to exercise
- chest pain
- dizziness
- breathlessness

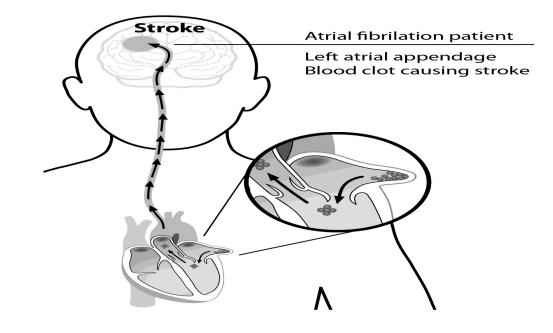
Treatment options to stop blood clots or stroke



The risk of a stroke depends on a number of factors. These include your age and sex. There is a greater risk if you have high blood pressure, heart failure, diabetes, or have had a stroke before or mini-stroke (TIA). Your doctor will be able to check your risk of stroke. They can recommend a blood thinner (anticoagulant) to stop blood clots forming. In a few people, a medicine called warfarin is used. Anticoagulants are known to cause side effects in some people. These effects include bleeding, some of them might be serious (like brain bleed, gastric bleed etc).

Another choice for some patients is to block the area where we know most blood clots from: the left atrial appendage. This can be done during surgery, for example, when having open heart surgery or with a medical closure device. This can be placed via the vein from the groin. The devices are designed to be permanently implanted in the left atrial appendage. This permanently closes it. This stops clots forming which can travel outside and cause stroke or other problems. The procedure is described in more detail in this leaflet.

Blood thinning medications are a common treatment for atrial fibrillation but they are not right for everyone. If you cannot take medication, your doctor might recommend procedure to close your atrial appendage.



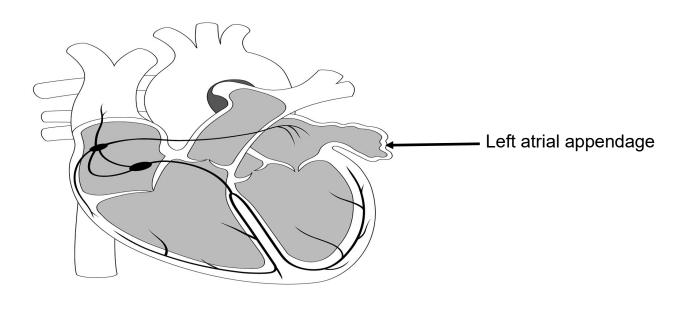
What is the left atrial appendage (LAA)?

Everyone has a left atrial appendage.

Left atrial appendage (LAA) is a small muscular pouch, found in the top left of your heart (left upper chamber (atrium).

It is 2 to 6 cm long, about the size of your thumb.

It is thought to be 'leftover' from the development of the heart. Studies have shown that in most patients with AF, almost all blood clots form in the left atrial appendage.



Why do I need a LAA (left atrial appendage) closure?

Your doctor may recommend a LAA (left atrial appendage) closure if you have a disease known as atrial fibrillation. This happens when your hearts electrical system is disturbed and your heartbeat becomes irregular. As your heart contracts with each heartbeat, blood is squeezed out of the upper chamber (atrium) and into lower chamber of the heart (ventricle). If you have atrial fibrillation, blood cannot be squeezed out of your left atrium well. It can pool in your left atrial appendage, where it can form clots. These clots can then be carried in the blood stream and can block small blood vessels in other parts of the body, such as in the brain which could cause to a stroke. The closure device is used to prevent blood clots forming in the heart.

Who should not get the device?

If you have any of the following conditions, you may not be a good candidate to get a closure device.

- If you have already blood clots in your heart.
- If you have an infection.
- If placement of the device would interfere with any other parts in your heart or its vessels.

What are the potential benefits of this procedure ?

- Reduce risk of stroke.
- Stop taking blood thinners and avoid side effects linked to them.

What are the potential risks and complications?

Every procedure carries some risks. These can be different for each person. There are a number of risks related to LAA closure which you have to think about before giving your consent to have the procedure done. The main risks are listed below:

Common risks:

- Bruising / discomfort at the place the catheter is inserted.
- 1 to 2.4 in 100 risk of stroke, heart attack or minor bleeding
- 1 to 5 in 100 risk of collecting fluid or blood around heart. This may need drainage or surgery
- 5 in 100 risks of minor vascular complications which may need intervention and device moving out of position after the implant.

Rare risks:

- Less than 1 in 1000 risk of death
- 1 to 5 in 100 risk of causing irregular heartbeat (arrhythmia), contrast related kidney damage and of infection.

- Less than 1 in 1000 to 10,000 risk of radiation induced cancer by using X-ray machine for the procedure.
- 1 to 9 in 100 risk of incomplete closure of the left atrial appendage and blood clot forming on the device. You may need to take blood thinners for a long time
- 2 in 1000 risks of damage to the gullet (oesophagus) during Transoesophageal Echocardiography

There may be some extra procedures that are needed during the operation. These may include:

- Blood transfusion: very unlikely
- Other procedure: Urgent support to stabilise your blood pressure. This helps blood flow within the organs and tissues in the body, or emergency heart surgery
- There is also a very low risk of complications from the general anaesthetic
- The device can be successfully implanted in between 88 and 95 out of every 100 cases.

What happens before the procedure?

- The medical team, which is made up of a number of staff will talk about your case and decide if treatment is needed
- You will meet with a cardiologist who does the implant to talk about your history and the procedure
- If you agree to proceed with the LAA closure you will be asked to come for a pre-admission appointment with a nurse a week or few days before the procedure
- We will talk to you about your past medical history and the tablets you are taking. It is important that you bring a list of your all your tablets with you. If you do not have a list, just bring the tablets
- If you are taking any blood thinning medication please let us know as you may need to stop these
- Please tell the nurse if you have any allergies
- We will also do an electrocardiogram (ECG), blood tests, blood pressure and swabs for MRSA bacteria and a CRO swab if you have had any hospital admission in the last year. We will explain the procedure to you, and you can ask questions
- We will give you a body wash (Stellisept) and nose cream. You use this for the 2 days before you come in. We will explain this to you. This is important as it reduces your risk of getting an infection.

Giving your consent for the procedure

We will ask you to give your legal consent by signing a consent form. This is either when you see the operating cardiologist at your outpatient appointment, or during you admission for the procedure. It is very important that you ask any questions or raise any concerns that are on your mind before signing.

What happens on the day?

- You will need to fast before your procedure. You must not have solid food from 6 hours before your procedure. All fluids must be stopped 2 hours before the procedure.
- Please bring your current medication or recent prescription.
- It is a day case procedure and you will be sent home the same day or next day morning. Please bring a overnight stay bag if any complications arise after the procedure and you need to stay.

What happens when I arrive on the ward?

Your admission time on the day of your implant will be **7:30 am** to a day case ward.

On arrival at the ward you will be shown to our waiting room. You will then be seen by a nurse who will:

- discuss your medications.
- may take a blood sample.
- record your heart rate, temperature and blood pressure.
- shave your groin, and chest if needed.

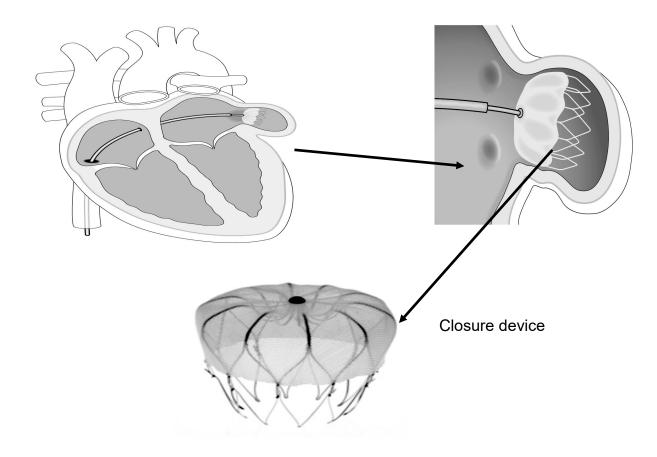
You will then be seen by one of the implant team and:

- have the procedure explained. Be asked to sign your consent form.
- may have antibiotics prescribed if needed (please tell us if you have any allergies).

The procedure

- 1. The LAA closure procedure is done under a general anaesthetic. This means you will be pain free and asleep for the procedure.
- A small ultrasound probe is placed in your food pipe (oesophagus), or alongside heart catheters. This is to look inside the heart and get some pictures of the atrial appendage to measure its size and shape and make sure the closure device can be put in the right place. This is called a transoesophageal echocardiogram (TOE) or ICE (intracardiac echocardiogram).
- 3. A flexible tube (guide sheath) is inserted into a large vein in the groin. This is threaded up to the right upper chamber (atrium) of the heart.
- 4. It is then passes through a hole in the wall that separates at the right and left chambers. In some patients this hole exists naturally. If it does not the doctor will make a small needle hole to allow the sheath to pass in to the left atrium. This hole as well as the one into vein in the groin heals naturally after the procedure.
- 5. The doctor then places the guide sheath in front of the LAA.

- 6. The device is then passed through the guide sheath and implanted to close the appendage
- 7. When the doctor is satisfied with the positioning of the device and closure (occlusion) of the appendage, they will release the device to leave it permanently implanted in your heart.
- 8. The procedure is guided by X-ray and echocardiogram (ultrasound of the heart via a probe in the gullet), to make sure the device is placed safely and correctly.
- 9. The procedures takes about 1 hour.
- 10. If during the procedure we find a clot in the LAA, we may not do the procedure.



After the procedure

- The sheath in the top of your leg will be taken out after the procedure.
- You will need to stay on bed rest for 2 to 4 hours.
- The ward nurses will continue to check you and check the small wound at the top of your leg (groin), as there is a small risk of bleeding or swelling.
- You may be quite sleepy on your return to the ward as a result of the anaesthetic. As soon as you are awake enough, the nurses will get you something to eat and drink. You will usually be given sips of water first.
- After a few hours of bed rest, you will be able to get up and move around the ward.
- You may have some bruising and discomfort in your groin. The small cut in the top of your leg. This may bleed slightly after the procedure.

• The recovery process will likely be quick and easy as the procedure needs only a small cut in the groin. Immediate recovery after the procedure will take about 24 hours. You will be discharged home on the same day or the next day.

Going home after the procedure

- You will be given a discharge letter. This will say what has happened to you in hospital and which tablets you are on. A copy of this letter will be send to your GP.
- You will need to continue to take the blood thinning tablets to thin your blood and stop large clots forming on the device. How long you need to take these for will vary.
- Your discharge letter will explaining why you are taking these tablets, and for how long you should take them.

For 24 hours after your procedure

- Do not drive or ride a bicycle/ car
- Do not operate machinery or do anything requiring skill or judgement (including cooking)
- Do not drink alcohol
- Do not take sleeping tablets
- Do not sign any legal documents, make any important decisions, or sign contracts.

After 24 hours

- The dressing over the cut can be removed after 24 hrs. It does not need to be replaced. You may replace with a fresh dressing for comfort.
- You should check the puncture site daily for the first few days once you get home.
- You may have some bruising but there should be no swelling. If you notice swelling please contact the team on **0795 987 0853 or 0116 258 3361** Monday to Friday 08:30am to 4:30pm or NHS Direct on 111 for advice
- We recommend you avoid any heavy lifting, pushing, or pulling for 3 days as this may cause pressure in the wound site and cause bleeding.
- Every person recovers differently. Generally, if you remain comfortable then moderate levels of exercise are allowed after 1 week.
- No baths, swimming, or hot tubs for 7 days. You may shower after 48 hours.
- Most patients return to work within 1 week (If you have a physical job talk to your consultant about when you can go back to work and how long you should avoid heavy lifting).

Common side-effects after the procedure

• Tenderness or a small bump (size of a 2 pence coin) at the wound site.

- Bruising or slight bleeding at the insertion site is also common.
- Possible feelings in the chest: palpitations, chest discomfort, or pressure. This is not uncommon for about 2 to 6 weeks after closure.

It is rare to have severe bleeding from the wound site once you are home. If bleeding does happen you must:

- lie down
- put pressure on the wound site and ask someone to call 999.

You should get urgent medical advice if you feel unwell after the procedure with symptoms of:

- your leg is painful, cold, red, swollen or has changed colour
- you have a fever
- white or yellow discharge coming out of the wound
- you suddenly feel short of breath or have trouble breathing
- you have severe pain or swelling at the puncture site (wound) or in your lower abdomen above the wound
- you have severe chest pain
- dizziness or fainting

Follow-up appointment

We will arrange an ECHO test 6 to12 weeks after your procedure to check for any leakage.

You will be reviewed by your stroke consultant in the outpatient clinic 6 to 12 months after the procedure.

If you were originally referred from another hospital, the follow-up will be arranged locally.

Driving

The Driver and Vehicle Licensing Agency (DVLA) state that you must not drive for at least for 4 weeks. You do not need to inform the DVLA . Talk to your consultant if you have any worries about this.

HGV license holders must not drive for 3 months and must notify DVLA.

We do advise you to tell your insurance company to avoid problems with any claims you may make in the future.

Does it work?

According to the current information, for those patients able to take blood thinners (anticoagulants), LAAC may be equally effective to OAC drug therapy for stroke prevention, but does not cause long-term bleeding complications .

Is it safe?

Yes. There is a small immediate risk related to the procedure. However, in experienced hands, this is considered a safe procedure, similar to other routine catheterization procedures .

Is atrial fibrillation going to stop after left atrial appendage closure?

No. LAAC is a stroke prevention therapy and does not cure AF.

Is left atrial appendage closure a lifelong solution?

Yes. A device will achieve lifelong closure of the LAA. Over months, the surface of the device will be covered by the patient's own tissue forming a smooth layer in continuation with the inner surface of the heart. This greatly reduces the likelihood of blood clotting on the device.

Do I need antibiotic treatment to prevent device infection?

During the implantation, a single dose of antibiotics is administered. After the procedure, antibiotic prophylaxis (for more invasive dental procedures, etc.) is recommended for a period of 6 months. After that antibiotics are not needed.

How about the long-term safety?

Late complications are very rare. The most common is clotting on the LAAC device, which is typically treated with a short period of Oral Anticoagulation therapy.

Do I need to be hospitalized for the procedure?

We plan same discharge but you may need to stay overnight if any issues.

Is the procedure painful?

The procedure is not painful. It is performed through catheters, with a 4–5 mm incision of the skin in the groin. Pain after the procedure is unlikely, but a few days of avoiding vigorous activities is recommended to allow this small incision to heal.

Can the device be removed from the left atrial appendage?

The device becomes firmly attached to the tissue after it is inserted. The only way to remove it is by (minimally invasive) heart surgery, although this is rarely needed.

Will LAA closure prevent strokes?

While there is no certain way to prevent strokes, blocking your LAA reduces your risk a lot. This is because 90% of strokes start in an upper heart chamber, in your LAA. According to research patients having an LAA closure devices have a lower risk of stroke.

Will I able to feel the device?

No, you will not able to feel the device once it is implanted.

Will I have a problem when travelling abroad?

The metal parts of your device are very small and do not trigger metal detector alarms. The sensitivity setting of the metal detector and other factors may affect how the metal detector responds to your device.

Will I stop taking blood thinners?

Yes. A few weeks after LAAO, the majority of patients may stop blood thinners. For some weeks you need to take a low-dose aspirin and/or clopidogrel therapy, until the closure device is covered with the your own body tissue and healed. If you also have a reason other than AF for taking the blood thinners or antiplatelet therapy, you may have to continue the treatment.

Will medical equipment interfere with my device?

Although most medical equipment will have no effect on your device, it is best to tell hospital staff that you have an implanted device before you have any medical procedure. Magnetic resonance imaging (MRI) scans are generally acceptable, but, please tell the staff about your implant.

Is it possible for the device to dislodge?

This complication is very rare and it is manageable. A dislodgement after the healing phase is highly unlikely.

Glossary of terms

Cardiac catheterisation: Something that is done to look at how well your heart is working. It is also to find out if you have disease of the heart muscle, valves or coronary (heart) arteries. During this test, doctors put a long, narrow tube (catheter) into a blood vessel in your arm or leg and guides it to your heart with the aid of a special X-ray machine. Doctors use contrast dye that they inject into your blood vessel through the catheter to create X-ray videos of your valves, coronary arteries, and heart chambers.

Catheter laboratory (Cath Lab): An examination room in a hospital or clinic. It has diagnostic imaging equipment used to picture the arteries of the heart and the chambers of the heart and treat any stenosis or abnormality found.

Contrast dye: this is a solution that radiologists use to see your organs and tissues more clearly in medical images such as X-rays, MRI and CT scan.

Carbapenem-resistant organism (CRO): It is a group of bacteria that are resistant to antibiotics called Carbapenems. Carbapenems (such as meropenem, ertapenem, imipenem) are a broad-spectrum group of antibiotics that are often relied on for infections where treatment with other antibiotics has failed. Carbapemen Resistant Organisms (CRO) can live in the gastro-intestinal tract (gut) of people and animals. In most cases CRO are harmless and cause no ill effects. This is called colonisation. CRO can cause a range of infections linked with healthcare such as wound, blood stream, urinary tract and respiratory tract infection and infections linked with invasive procedures or devices

Direct oral anti-coagulant medication (DOACs): A new oral anticoagulant.

Electrocardiogram (ECG): A simple test that can be used to check your heart beat and electrical activity. Sensors attached to the skin are used to find the electrical signals produced by your heart each time it beats.

Echocardiogram (echo): An echocardiogram uses sound waves (ultrasound) to build up a moving picture of your heart and shows the structure and function of your heart valves and heart chambers. An echocardiogram takes around 20 minutes.

Haemodynamic support: Medications are used to keep your blood pressure and heart rate within the normal range.

Left atrial appendage(LAA) The left atrial appendage is a small pouch in the left chamber (atrium). It is a site where blood clots mainly form in atrial fibrillation.

Methicillin-resistant staphylococcus aureus (MRSA): An infection caused by a type of staph bacteria. It has become resistant to many of the antibiotics used to treat ordinary staph infections.

Percutaneous: this is a method to check the inner organs through a needle puncture of the skin.

Transoesophageal Echocardiogram (TOE): a test is sometimes done to take clearer pictures of the heart using a probe down your throat. You will be asked to lie down and swallow the tube. You may be given some drugs to help you relax before this is done.

More information

NHS 111

Offers medical help and advice from fully trained advisers supported by experienced nurses and paramedics. Available over the phone 24 hours a day.

University Hospitals of Leicester: <u>www.leicestershospitals.nhs.uk</u>

NHS England: 1692-left-atrial-appendage-occlusion.pdf (england.nhs.uk)

Patient Information Forum

National Institute of Health and clinical Excellence: <u>Overview | Percutaneous occlusion of the left</u> <u>atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism | Guidance | NICE</u>

Atrial Fibrillation Association: heartrhythmalliance.org/afa/uk/

National Institute of Health and clinical Excellence: <u>Overview | Atrial fibrillation: diagnosis and</u> <u>management | Guidance | NICE</u>

Contact details

LEICESTER'S

Structural Heart Valve Specialist Nurse: 0795 987 0853

Structural co-ordinator: 0116 258 3361

Hospital switchboard: 0300 303 1573

If you have any questions, write them down here to remind you what to ask when you speak to the nurse/consultant.

اگر آپ کو یہ معلومات کسـی اور زبان میں درکار ہیں، تو براہِ کرم مندرجہ ذیل نمبر پر ٹیلی فون کریں۔ علی ھذہ المعلومات بلغةٍ أُخری، الرجاء الاتصال علی رقم الهاتف الذي یظهر في الأسـفل જો તમને અન્ય ભાષામાં આ માફિતી જોઈતી ફોય, તો નીચે આપેલ નંબર પર કૃપા કરી ટેલિફોન કરો

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If you would like this information in another language or format such as EasyRead or Braille, please telephone 0116 250 2959 or email equality@uhl-tr.nhs.uk

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