Royal Papworth Hospital
NHS Foundation Trust

# Implantable left ventricle assist device (LVAD)

## A patient's guide and consent form

Compassion
Excellence
Collaboration

## Introduction

This information booklet has been prepared to help you and your relatives understand the implantable left ventricle assist device (LVAD) operation and what the risks and benefits of having the procedure will be for you.

## Summary

An implantable LVAD is a mechanical blood pump that is placed inside the body and supports your circulation. Implantable LVAD are used as a bridge to heart transplantation in patients with advanced heart failure. Most patients feel better with LVAD support and some notice a dramatic improvement. Most patients go home within a couple of weeks and go on to receive a heart transplant in future years. Serious adverse events can arise during LVAD support. We will support you along your journey, no matter what happens.

A member of our team will talk you through this information in detail. We will support you to make an informed decision about having an implantable LVAD. The decision will not be easy because it will be life-changing. If you decide to go ahead, then we want to help you get ready to enjoy life with your LVAD. Please read through this booklet carefully and discuss any questions or concerns with our team.

## Why am I receiving this booklet?

As you will be aware from discussions with our team, you have advanced heart failure. This is a serious condition. The most common symptoms are tiredness, breathlessness and fluid retention. Your exercise capacity is likely to be severely reduced. You may have been admitted to hospital with worsening heart failure or life-threatening heart rhythm disturbances. Sadly, patients with advanced heart failure are at high risk of death. For these reasons, we are thinking about heart transplantation and implantable left ventricular assist device (LVAD) support. These treatments represent our best chance of restoring your quality of life and life expectancy.

## What is an implantable LVAD?

An implantable LVAD is a mechanical blood pump that works alongside the main pumping chamber of your heart (left ventricle) to circulate blood to your vital organs. The pump is connected to an electrical cable (driveline) which exits the body near the umbilicus (belly button). The driveline is connected to a system controller and batteries, which provide the LVAD with power. An overview of the LVAD system is provided in figure one.

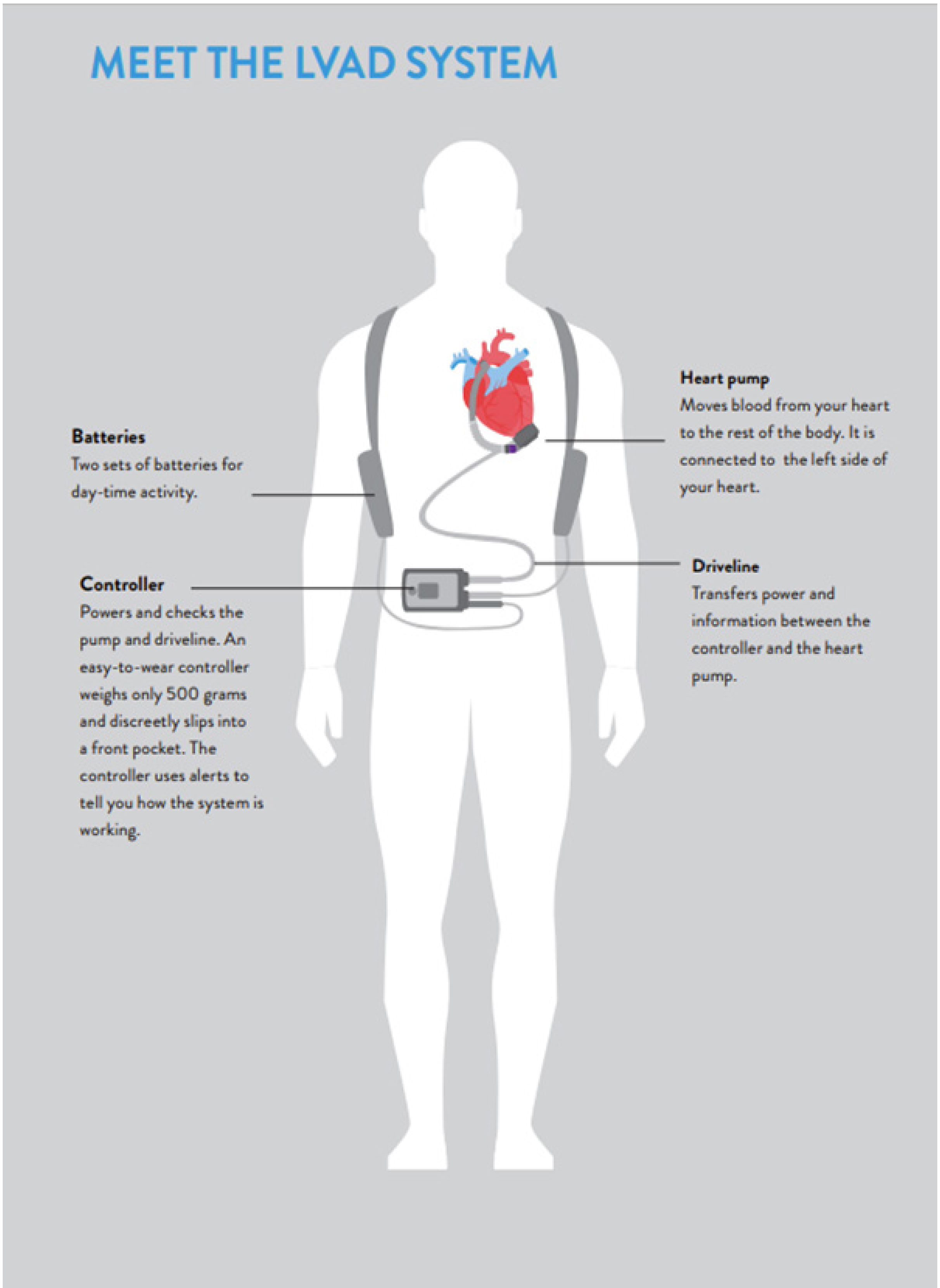
Implantable LVAD are used as a bridge to heart transplantation in the UK. This means that we might recommend an LVAD if:

- Your heart is not able to pump enough blood around your body and we think you may die or develop failure of other organs before we are able find a suitable donor heart for transplantation.

- The resistance to blood flow through your lungs is too high to allow safe heart transplantation but we think that this problem can be reversed by the LVAD so you can safely have a heart transplant in future.

It is important to know that the LVAD should significantly improve your circulation while you are waiting for a heart transplant. Your heart failure symptoms, such as breathlessness and tiredness, are likely to improve significantly. You should have more energy to resume many of the activities you used to enjoy. Your quality of life should improve. Most of our patients live well with their LVAD for years and most patients go on to have successful heart transplants.

The pictures in the next pages provide an overview of the components used to support the LVAD pump and patients.



MEET THE LVAD SYSTEM

**Batteries**
Two sets of batteries for day-time activity.

**Controller**
Powers and checks the pump and driveline. An easy-to-wear controller weighs only 500 grams and discreetly slips into a front pocket. The controller uses alerts to tell you how the system is working.

**Heart pump**
Moves blood from your heart to the rest of the body. It is connected to the left side of your heart.

**Driveline**
Transfers power and information between the controller and the heart pump.

Figure one
*Image courtesy of Abbott, used with permission.*

| | | | |
|---|---|---|---|
|  | Shower bag |  | External batteries |
|  | Consolidated bag |  | Mobile power unit |
|  | Waist<br>belt attachment |  | Battery charger |
|  | Holder vest |  | Controller |
|  | Pump |  | Pump |

Figure two
*Image courtesy of Abbott, used with permissions*

## Getting ready for the operation

Getting ready for the operation depends on your condition. Some patients will already be in hospital. Other patients will be admitted in the days before surgery. We may stop some of your medications before surgery, such as anti-coagulation or adjust some of your heart failure medications. We may want to repeat tests such as an echocardiogram or a right heart catheter. You will need to use skin preparation before surgery. This process is called decolonisation and eradicates certain bacteria which live on the skin and can cause infection after your operation. Finally, we start teaching you to look after your LVAD, so that this is familiar after your operation. Most patients find this reassuring.

## The anaesthetic team

The anaesthetic team will meet you either in the critical care area (CCA) or in the operating department. The team is led by a consultant anaesthetist and may include junior anaesthetic doctors, operating department practitioners (ODP) and anaesthetic nurse-specialists. The anaesthetic team will ask you about previous anaesthetics, other medical problems, medications and allergies. They will ask you about any fragile dental work, mouth opening or neck mobility issues and swallowing difficulties. They will answer any questions that you have about the anaesthetic, the lines that will need to be inserted and pain relief after the operation.

**It is very important to let us know if a rare and life-threatening condition called malignant hyperpyrexia runs in your family as this requires special preparation before an anaesthetic.**

You will lie down on the operating table and monitoring equipment will be applied. These include small ECG stickers on your skin and a probe on your finger to monitor your heart rate and oxygen levels. Any dentures will be removed, and you may be given oxygen to breathe. The anaesthetist will insert a thin plastic tube (cannula) into a vein on the back of your hand or forearm. If needed, you will usually be given a small dose of a sedative medication which may make you feel relaxed. A second cannula will be inserted into an artery, usually in your wrist or arm crease. This is used to measure blood pressure and allows blood tests to be taken. Local anaesthetic will be used to numb the skin before insertion of the arterial cannula and may also be used for the venous cannula. Your anaesthetist will then slowly inject anaesthetic drugs. These render you unconscious and you should not be aware of anything until you wake up after the operation. Awareness (not being properly asleep) during the operation is extremely rare (around 1 in 20,000 procedures from a national audit). Your anaesthetic team will be present the whole time and monitor you carefully. If you are worried about this, please ask your anaesthetist. There is a link to further information in the resources section at the end of this booklet.

Once you are asleep, the anaesthetic team will place a breathing tube through your mouth and into your windpipe. A ventilator is then used to blow a mixture of oxygen, air and anaesthetic gases into your lungs. A specialised cannula, called a central venous catheter (CVC), will be inserted into a large vein in your neck. This is used to give fluid and medications and measure venous pressure. A pulmonary artery catheter (PAC) may be inserted. This measures blood pressure in the lungs and monitors the function of the heart. Sometimes additional lines are placed into the groin either for monitoring, to administer fluids or medications. Most of these lines stay in for a few days after surgery. A transoesophageal echocardiography (TOE) probe will be passed through your mouth and into your food pipe (oesophagus). It is used to take ultrasound pictures during the operation. The risk of injury from this probe is low (around 1 in 1,300 procedures from a national audit). These injuries can be serious, may result in need for further operations or can result in death.

**It is important to tell the anaesthetist if you have had surgery previously on your throat, food pipe or stomach, have any difficulties swallowing or have been told that you have a pharyngeal pouch, a hiatus hernia or problems with your food pipe.**

A temperature probe will be inserted into your nose or mouth to continuously monitor your temperature. Occasionally it can cause bleeding from the nose. Let your anaesthetist know if you have had problems with nosebleeds in the past as this probe can be put in a different place if needed. A tube (catheter) will be passed into your bladder to drain urine and monitor how much urine is being produced by the kidneys. This will be inserted whilst you are asleep and will stay in after the operation for a few days. Occasionally this can cause infection, bruising or bleeding. Let your anaesthetist know if you have an enlarged prostate (men) or have experienced problems with urine catheters in the past. Occasionally it is necessary to insert this through the front wall of the lower abdomen into the bladder (a suprapubic catheter).

## The LVAD operation

Once you are asleep and all the monitoring equipment is in place, then the surgeons start the operation. First your skin is cleaned, then you are given antibiotics and an anti-fungal medication for prophylaxis. An incision is made along your breastbone (sternum) to access the heart (sternotomy). Sometimes an incision is made between two ribs (thoracotomy). The surgeons place large plastic tubes (cannulae) into large arteries and veins. These tubes are used to divert blood into a heart-lung bypass machine. The blood is returned, under pressure, into the arterial system. This machine pumps oxygen-rich blood to all your vital organs during the operation, taking over the work of your heart and lungs while you are having the LVAD implanted.

A sewing ring is attached to the apex of the heart. A hole is made through the centre of the sewing ring and the pump is connected to your heart. The inflow pipe sits within the left ventricle, and the rest of the pump sits outside the heart. The outflow graft is attached to the aorta which is the body's main artery. The driveline will be tunnelled internally through the abdominal wall and exits on the lower part of the abdomen, close to your belly-button. This driveline is connected to the LVAD system controller and external power source.

Once the LVAD is implanted, you will be weaned from the heart-lung bypass machine and the LVAD settings will be optimised for your body's needs. It is normal for you to need support with intravenous and inhaled medications at this stage. These medications are called inotropes. They are used to support the heart immediately after the surgery.

A temporary right ventricular assist device (RVAD) may be needed if the right ventricle is struggling to pump blood after the LVAD has been implanted. Temporary RVAD may be placed directly into the heart or central blood vessels or through peripheral blood vessels, such as those in the groin. Temporary RVAD may be used for days, weeks or months. Some devices can also be used with an oxygenator to support your lungs if required. In the last six years, 7% of patients have needed a temporary RVAD after LVAD implantation at Royal Papworth Hospital.

Once your condition is stabilised in theatre, several plastic tubes (drains) are placed around the heart and in the pleural space around the lungs to drain any blood that accumulates over the subsequent days. Fine pacing wires may be attached to the heart to regulate heart rhythm. The breastbone is joined together with wires and the wound closed with stitches. The resulting scar in most people will eventually look like a fine line.

## What happens immediately after surgery?

Once the operation is finished, you will be transferred to CCA located opposite the operating department. CCA is a specialised area where we look after patients who are recovering from surgery. You will meet a large team of healthcare professionals.

Once the CCA team is confident that you are stable, then the anaesthetic medications will be switched off to allow you to wake up. You will continue to be given painkilling medication. You may feel disorientated and sleepy when you wake up. You will still be connected to monitoring equipment, which can be noisy, and have drips in your arm and neck. There will be drains and pacing wires in place. At first you will still have the breathing tube in your mouth, and because this passes through your voice box you will not be able to speak. You will still be able to answer 'yes/no' questions by nodding or shaking your head. When the team caring for you are confident that your breathing is stable and the anaesthetic has sufficiently worn off, the breathing tube will be removed and replaced with an oxygen mask. It is unusual to be fully awake and have the breathing tube in place for a long period of time. Many patients do not remember waking up with the tube still in place.

Strong painkillers will be given to you through a vein as part of your anaesthetic and are continued until after you wake up. Your nurse will regularly assess you to ensure you have adequate pain relief. Once you are awake, they can often be replaced by tablet painkillers. Patients occasionally require ongoing intravenous pain relief, and this can be provided using a patient-controlled analgesia (PCA) machine. A PCA allows you to give yourself a small dose of strong painkiller by pressing a button. If you are in any discomfort or pain after surgery, please let your nurse know. It is important not to allow pain to continue after your operation as it can hinder deep breathing and rehabilitation.

## Next steps in the critical care area

It is common to need support in the critical care area in the early days after your LVAD has been implanted. You might need support for a longer period if there were problems with your right ventricle, if there were problems with other vital organs such as the lungs, kidneys, liver or brain, or if there were issues with infection. Monitoring and treatments that may be needed include but are not limited to:

- **Arterial catheters** are fine plastic tubes placed in an artery in your arm or leg that allow blood pressure to be monitored. They are removed when we are confident that your blood pressure can be measured non-invasively.

- **Venous catheters** are fine plastic tubes that are placed in a vein in your neck, leg or arm. They are used to administer medications and measure venous pressure. A specialised pulmonary artery catheter is used to manage your LVAD pump speed and make decisions about medications to support your circulation. All catheters are changed regularly to reduce the risk of infection.

- **Inotropes** are medications that increase the contractile function of your right ventricle and support your blood pressure. They are used in almost all patients during the first few days after LVAD implantation.

- **Anticoagulation** is used in all patients with implantable LVAD to reduce the risk of blood clot formation within the body and blood pump. We typically start with intravenous medicine called heparin and later switch to an oral medication called warfarin. All anticoagulant medications are associated with a risk of bleeding. You will be continually monitored for signs of bleeding.

- **Nasogastric tubes** are passed through the nose into the stomach to allow feeding. They are commonly used if you are sedated and cannot eat or if you are finding it difficult to eat enough for your needs.

- **Temporary dialysis** using a technique called continuous haemofiltration may be used to support your kidneys. A tube will be placed in a central vein in your neck or groin. Blood is taken out of your body, passed through the haemofilter, and then returned to your body.

- **Ventilation** is use of a machine to support your breathing via a breathing tube. Most patients are sedated, but sedation is deliberately reduced at times. When sedation is lightened, you may be able to hear what is going on and respond to questions with head or limb movements. If you are uncomfortable, then sedation and/or painkillers will be increased.

- **Tracheostomy** may be needed if you require ventilation for a long time. A tracheostomy involves creating a small hole in the front of the neck through which a breathing tube is passed into the windpipe. It will leave a scar and comes with its own risks but has significant benefits for recovery and avoids problems caused by breathing tubes passed through the mouth.

As you recover from the implantable LVAD operation, the priorities of treatment change. We will get you out of bed, into a chair and then onto your feet and walking around the CCA. The CCA team will work with you daily and you will be regularly assessed by the physiotherapy team. We will encourage you to eat and drink, so that you are well nourished. We will offer you psychological support and talk to you about the next steps of your journey. Once recovered from the surgery you will be transferred to a surgical ward (usually ward 5 North) to continue your recovery, rehabilitation and training.

## Learning to live with your implantable LVAD

Living with an implantable LVAD is a life-changing event. Training will be provided by our LVAD specialist nurses. We will teach you and your care-givers to manage your implantable LVAD. We want you to feel confident and able to manage all aspects of living with an implantable LVAD. Training will include:

- Introduction to all the LVAD system components, including system controller, mobile power unit and battery charger
- Changing power source, including connecting to mains and batteries
- Changing system controller
- How to respond to system controller alarms
- How to use different accessories "wearable accessories"
- How and when to change dressings
- How and when to shower
- How to measure your INR and send us results
- Diet (some foods can increase and/or decrease effect of Warfarin)
- Our contact details
- What to do in the event of an emergency

## Preparing for discharge

We will plan your discharge once your training is complete and our team are happy that you are ready to go home. We will arrange training sessions with your GP and family. These sessions can be face to face and/or virtually.

**The LVAD team can be contacted from Monday to Friday 08:00 to 18:00 via the hospital switchboard (01223 638000) on bleep 235 or via email using the address papworth.mcsd@nhs.net.**

In the event of problems outside these times, a transplant coordinator is on-call from 18:00 to 08:00 during weekdays and 24 hours per day during weekends and bank holidays. They can be contacted via hospital switchboard 01223 638000.

## Coming back to the outpatient clinic

We will review you regularly in our outpatient clinic after discharge. Visits are individualised. Appointments become less frequent as you recover and become more confident with your LVAD. If there are problems, then we may need to see you more frequently. A typical schedule of outpatient appointments is:

- Every week during months one and two
- Every two weeks during months three and four
- Every month during months five and six
- Every three to four months thereafter

On each visit, you will be reviewed by an LVAD specialist nurse and a cardiologist. If necessary, you may see a surgeon, tissue viability nurse, physiotherapist, clinical psychologist or diabetes specialist nurse. You will have tests during clinic visits to monitor your health and progress. You are likely to have blood tests, an ECG and a chest x-ray at most appointments. You will also need to have an echocardiogram and right heart catheterisation at regular intervals.

We expect you to attend all your scheduled clinic appointments. Failing to attend appointments without good reason, or not following our recommendations, can increase your risk of adverse events or death during LVAD support. It can also compromise your eligibility for heart transplantation.

## Medical aspects of living with an implantable LVAD

**Driveline care** is vital. We want you and your caregiver to be independent with dressing changes, so there is continuity in checking for infection. Dressing changes should be performed at least twice per week. We will provide a supply of dressings at discharge but these will be supplied by your GP in the longer term. Specialised dressings to secure the driveline (hollisters/cathgrips) will always be supplied by Royal Papworth Hospital.

**LVAD system controller and power supply** are essential for your LVAD to keep you alive. In turn, you need to look after the LVAD system controller and power supply. It is vital to take backup equipment when you travel away from home. It is important to understand how to respond to any system controller alarms.

**Blood pressure** is more difficult to measure after your LVAD has been implanted. The pump generates continuous blood flow and most patients can no longer feel peripheral pulses. Automatic blood pressure machines do not work reliably. We will show you how your blood pressure can be measured with a manual blood pressure cuff and small machine called a handheld doppler probe.

**Medications** are also essential after your LVAD has been implanted. These control fluid balance, blood pressure, and reduce the risk of blood clot formation associated with the pump. You are responsible for ensuring that you have an adequate supply of medications. You will be given a supply of medications at discharge but will have these prescribed by your GP thereafter. It takes two to three working days for repeat prescriptions to be issued, so don't wait until you have a few tablets left. If we make changes at an outpatient clinic, then we can give you a hospital prescription but please ensure that your GP updates your repeat prescription.

**Anti-coagulants (usually warfarin)** are essential to prevent blood clot formation in the pump. A clot could lead to stroke or pump failure. Warfarin must be monitored with regular blood tests (INR). We will provide you with a home INR monitor (Coagucheck ®), train you to use this device and explain how to send your results. We will tell you if your warfarin dose needs to change and when your INR needs to be checked again. If your INR is too low, then you may need to take an injectable anti-coagulant called low molecular weight heparin (LMWH) until the INR is back in range. We will show you how to do this.

**Exercise** is important for your recovery. Our team will help you develop an exercise programme. This may include a referral to a local cardiac rehabilitation programme. Exercise will improve your stamina and quality of life with your LVAD. It will reduce the risk of weight gain.

**Pacemakers and most ICDs** remain in place after your LVAD is implanted. We are likely to reprogram your ICD so that it works appropriately alongside your LVAD. You will continue to receive pacemaker or ICD checks at your local device clinic. You will need to arrange these appointments; we do not book them for you.

**MRI scans** are not possible with an implantable LVAD because the strong magnetic field would interfere with the LVAD function.

## Returning to usual activities with your LVAD

Living with your implantable LVAD will become a familiar routine, but takes some getting used to. Most patients have gradually returned to usual activities by 3 months after surgery. Planning ahead is essential to ensure that you always have what you need, no matter where you are going or what you are doing. It is important to raise any questions or concerns about your recovery during your clinic visits. We are happy to answer any questions about living with your LVAD.

**Showering** is usually possible from three months after surgery, once we are satisfied that your driveline is fully healed. We will show you how to use the shower bag.

**Bathing, swimming, contact sports and jumping** are all prohibited because of risk to the driveline, system controller and batteries. The system controller and/or batteries must not be submerged in water under any circumstances.

**Sex and intimacy.** You should be able to return to sexual activity as your condition improves after your LVAD has been implanted.

**Working** in a physicial job is not recommended during the first three months after LVAD implantation. Patients with a desk-based role may return to work sooner if they are ready. Your employer may need to perform risk assessment before you can return to work, particularly if you perform a physical job. We can issue you with a hospital inpatient form (Med 10) for the period that you are in hospital. We can also issue you with a statement of fitness to work form (Med 3, fit note, sick note) after discharge, but these are usually issued by your GP.

**Driving**. You must not drive after your LVAD has been implanted and must notify the DVLA. If you wish to return to driving, then you need to apply to the DVLA for relicensing. Group one (car and motorcycle) driving may be relicensed under individual assessment only after three months from implantation. Group two (bus and lorry) will be refused and revoked permanently. You also need to inform your motor insurer that you have an implantable LVAD.

**International travel** is possible. It is strongly advisable to have contact details for the closest LVAD centre to your destination in case of an emergency. Most airlines require notification about your LVAD, including details about your system controller, batteries and need for power during the flight. We can give you a supporting letter on request. It is highly recommended that you obtain travel insurance. If you are on the Transplant waiting list, then you will be placed on hold until you return to the UK.

## Moving on to heart transplantation

Implantable LVADs are used as a bridge to heart transplantation in the UK. We need to be honest with you. There is a major shortage of suitable donor hearts in the UK and waiting times for heart transplantation are long. For this reason, most patients wait for several years with their LVAD before receiving a heart transplant. Sadly, some patients die or experience adverse events during this time which means that heart transplantation is no longer possible or advisable.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

# PIC 264: patient agreement to PI 264 - implantable left ventricle assist device (LVAD)

## Statement of health professional

(To be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy). I have explained the procedure to the patient. In particular I have explained:

The intended benefits:

- ☐ Reduce risk of death
- ☐ Preserve function of vital organs
- ☐ Reduce lung blood pressure so you can have a heart transplant in future

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**Risks of an implantable LVAD**

The potential risks of an implantable LVAD are detailed in this document. Additional significant or unavoidable risks include the following:

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**Any extra procedures, which may become necessary during the procedure:**

☐

- ☐ Blood transfusion
- ☐ Return to operating theatre to manage complications

Other procedure – please specify below:

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I have discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment), and any particular concerns of this patient.

## Consultant/performer

Signed: ..........................................................

Date: ..........................................................

Name (PRINT): ..........................................................

Job title: ..........................................................

**Contact details**

If you require further information at a later date, please contact switchboard on 01223 638000 and ask to speak to your consultant's secretary.

## Statement of patient

Please read the patient information and this form carefully. If the treatment has been planned in advance, you should already have your own copy of which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

**Yes** **No**

☐ ☐ **I agree** to the procedure or course of treatment described on this form and have read this information leaflet on implantable left ventricle assist device (LVAD) (PI 264) and had the opportunity to ask questions.

☐ ☐ **I agree** to the use of photography for the purpose of diagnosis and treatment and I agree to photographs being used for medical teaching and education.

- **I understand** what the procedure is and I know why it is being done, including the risks and benefits.
- **I understand** that any tissue removed as part of the procedure or treatment may be used for diagnosis, stored or disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.

Top copy to be filed in medical notes, carbon copy to be retained in booklet for patient.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

- **I understand** that any procedure in addition to those described on this form will be carried out only if necessary to save my life or to prevent serious harm to my health.
- I have listed below any procedures **which I do not wish to be carried out** without further discussion:

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**I have been told in the past by Public Health that I am at increased risk of CJD (Creutzfeldt Jakob disease) or vCJD (variant Creutzfeldt Jacob disease).**

☐Yes ☐ No

(Where patient indicates 'yes' health professional to refer to Trust CJD procedure DN092)

## Statement of interpreter

If an interpreter was present to support this consent, please state the name and number of the interpreter present.

Date: .....................................................................

Interpreter's number:.................................................

Name (PRINT): .........................................................

If a telephone / video service has been used, please document the name of the interpreter and company below

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## Confirmation of consent

(To be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance).

**On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish the procedure to go ahead.**

Signed: ..........................................................

Date: .............................................................

Name (PRINT): ................................................

Job title: ........................................................

**Important notes** (tick if applicable).

☐ Patient has advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign/date here)

Patient signature: ..................................................

Date: .......................................................................

Name (PRINT): .......................................................

Top copy to be filed in medical notes, carbon copy to be retained in booklet for patient.

# Recommended summary plan for emergency care and treatment (ReSPECT)

## What is ReSPECT?

ReSPECT stands for 'Recommended summary plan for emergency care and treatment'. It is a process that helps people to think about what treatment is suitable in an emergency, should they be unable to make decisions at the time.

## Why is it important?

We know that, when people are very unwell, they are often unable to think clearly about what treatment they may or may not want because their brain and body are overwhelmed by the illness. It is also normal for people to feel anxious about what is happening when they are sick and in hospital, and this can also make it difficult to think clearly. This is why we think it is a good idea, where possible, for decisions about medical treatment to be made in advance – before there is an emergency situation or crisis.

## How does it work?

The ReSPECT process is designed to help conversations between you and your healthcare professionals: they need to make sure you understand your health problems and which treatments may or may not benefit you. You need to make sure the healthcare professionals understand what matters most to you and whether there is anything you are particularly worried about or would want to avoid.

This conversation is used to complete a ReSPECT form that records a person's health problems, their preferences and which medical treatments may or may not be suggested.  The original form should stay with the patient, though it is extremely helpful to have a record of the content of the form on their electronic patient record.

**A ReSPECT form is NOT a legally binding document and can be changed or withdrawn at any point.**

The ReSPECT form is often used to indicate treatments that someone may not want and/or treatments that their healthcare professionals consider would no longer be of benefit to them.

If people are getting worse from progressive conditions, it may be helpful to consider in advance about things such as whether they would wish to go back into hospital and, if in hospital, what sort of treatments might or might not be helpful for them.

This often includes a decision on whether or not they should have attempted cardiopulmonary resuscitation (CPR) if their heart was to stop.

## Who is it for / is this relevant for me?

This process has increasing relevance for people who have complex health needs, people who may be nearing the end of their lives and those who are at risk of sudden deterioration or cardiac arrest.

However, many people come to Royal Papworth to have major procedures or surgery with the intention of curing a progressive disease or with the intention of substantially prolonging their life and, if that is you, you may wonder how a ReSPECT discussion applies to you and others like you. One of the key things to understand about the ReSPECT process is that it can be used simply to document a person's wishes and priorities, without setting any limitations on what treatment they should have.

This is important because all the procedures and operations we do here come with the risk of complications. In the unlikely event that things do not go as planned, it is really helpful to have some idea about a person's preferences and about their fears, worries and hopes.

Once again, the document is not legally binding, but it can help those looking after you to know what you might want if you weren't able to say for yourself.

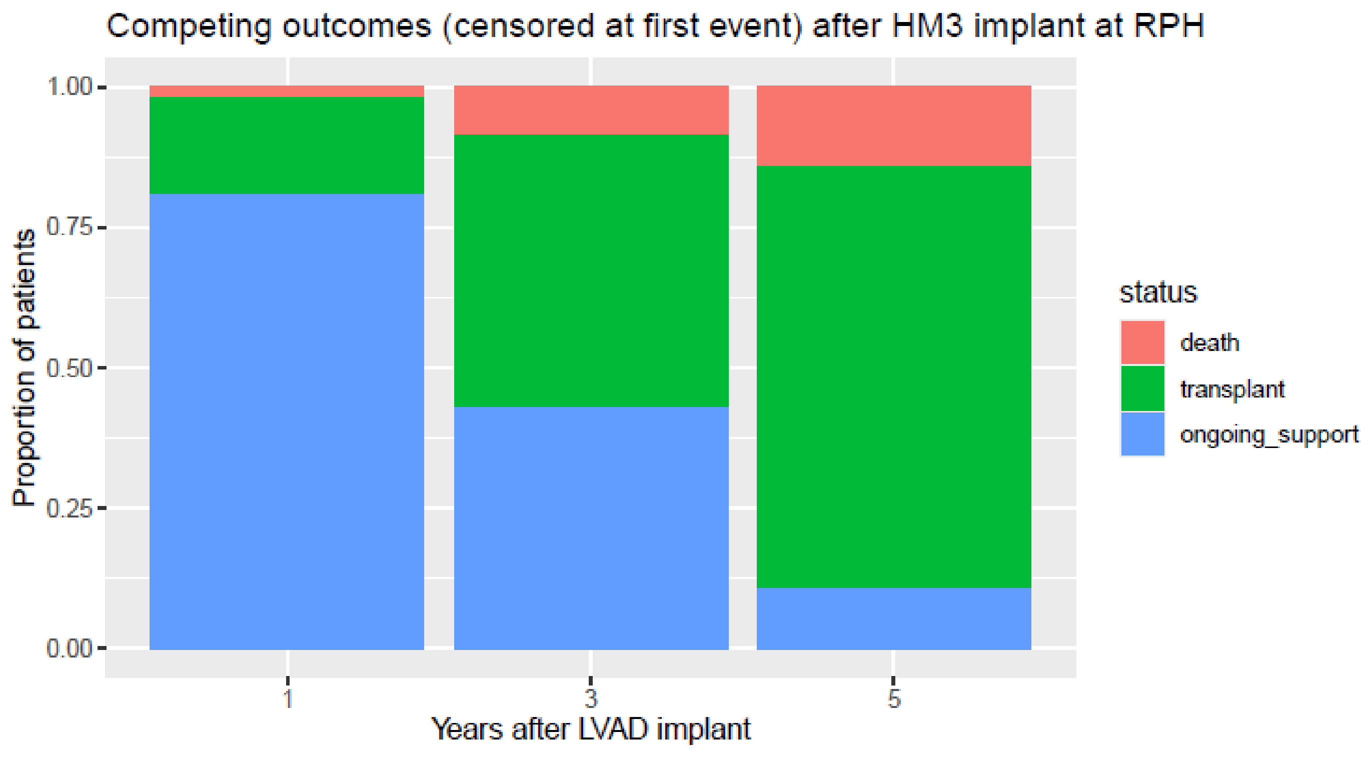
It is important to understand that we do not know your outcome at the start of your treatment.

If you are already on the heart transplant waiting list, then you will be placed 'on hold' after your LVAD is implanted. After surgery, you need to rehabilitate and recover. You will be re-evaluated for heart transplantation after three to six months. This process includes a right heart catheter and a CT scan. You would only be activated (or reactivated) on the heart transplant waiting list once the whole team is confident that you have recovered enough to safely undergo heart transplantation.

Since 2018, we have supported 61 patients with a Heartmate 3 implantable LVAD at Royal Papworth Hospital. Competing outcomes for these patients at one year, three years and five years after LVAD implantation are presented in number and graphic form.

Since 2018, the average time that patients were supported by an implantable LVAD before receiving a heart transplant was 1.49 years. However, this time varies between patients. Half of patients were supported for between 0.75 years and 3.36 years. Some patients were supported for longer periods of time until a suitable donor heart was available, and a few patients remain on LVAD support. Waiting time depends on factors such as height, weight, sex, blood group and antibody profile. It also depends on adverse events which might mean you are prioritised for a heart transplant or might mean that you can no longer receive a heart transplant.

| | After one year | After three years | After five years |
|---|---|---|---|
| Ongoing LVAD support | 81% | 43% | 11% |
| Transplant | 17% | 49% | 75% |
| Died during LVAD support | 2% | 8% | 14% |



*Statistics as of March 2025*

## What are the risks with implantable LVAD?

Implantable LVAD support is not successful for everyone. Adverse events occur during support. Adverse events may be fatal or could result in the development of a permanent contraindication to heart transplantation. Very rarely, an LVAD is implanted to reduce lung blood pressure but does not achieve this. In these situations, heart transplantation would not be possible and you would live with your implantable LVAD for the rest of your life.

Each patient is unique and will face different risks. It is our duty to explain the risks that an 'average' patient will face. Some risks are very individual, such as risks relating to previous heart surgery. It is important to recognise that we cannot describe every conceivable event that may occur. It is also important to understand that any of these adverse events could potentially result in death or prevent you from being suitable for a heart transplant.

Please remember that we will only recommend an implantable LVAD if we think that the benefits outweigh the risks for you. We will discuss your individual risks with you. Please ask a member of our team if you have any questions or concerns.

### Very common early risks

**These affect more than 10 in 100 patients**

**Bleeding.** This may require insertion of a drain, blood transfusion or further surgery.  Blood transfusion is safe but there are potential risks. Your team will offer you an information leaflet 'Will I need a blood transfusion? Patient information'.

**Acute kidney injury.** There are many potential causes of acute kidney injury after an LVAD has been implanted, including periods of low blood pressure, low blood flow, obstruction of blood flow due to blood clot or medications. This may require treatment with temporary dialysis (haemofiltration). If kidney function does not recover, then this can prevent you from going on to receive a heart transplant.

**Infection** may occur in the surgical wound, around the drains or elsewhere in the body such as your lungs, urine or blood (also known as septicaemia).

**Nausea and vomiting.** Anti-sickness medications are usually given at the time of surgery to reduce the risk and can be given as needed after surgery.

### Common early risks

These affect between 1 in 100 and 10 in 100 patients

**Stroke or other types of brain damage.** If brain function does not recover, then this can impair your recovery from surgery and reduce your quality of life with your implantable LVAD. It may also prevent you from going on to receive a heart transplant.

**Blood clots** in the veins of the legs known as deep vein thrombosis (DVT), or lungs pulmonary embolism (PE). You will receive blood thinning medication when this is appropriate to help prevent these.

**Heart rhythm disturbances** may require treatment with rhythm-controlling drugs, or a procedure called cardioversion to correct the heart rhythm.

**Partial obstruction of arteries or veins** due to the presence of plastic pipes can lead to bleeding and jeopardise blood flow to your arms, legs or other vital organs. This is termed ischaemia. Operations to remove blood clot (embolectomy) or relieve pressure inside swollen muscle compartments (fasciotomy) may be required. In very severe situations, loss of your arm or leg (amputation) may be necessary to save your life. Limb swelling and pain may persist in the longer term.

**Stress ulceration of the stomach or bowel.** This can lead to bleeding from the area of ulceration. All patients receive antacid medication to help reduce this issue.

**Altered bowel function.** Bowel function may be slow to normalise after surgery, leading to constipation or diarrhoea. Rarely bowel perforation may occur and this would require additional surgery.

**Bowel ischaemia.** Patients who are severely unwell may suffer from disruption of the blood supply to the bowel (ischaemia). Bowel ischaemia may require surgery to remove the affected bowel and this can be life-threatening.

**Acute liver injury.** Patients who are severely unwell may have periods of low blood flow or pressure which can affect liver function. Severe liver failure is life-threatening.

**Heparin-induced thrombocytopenia (HIT).** This is an allergic reaction to an anticoagulant medication (heparin) that we use in the first few days after your LVAD has been implanted. HIT can lead to bleeding or blood clotting problems.

**Critical illness neuropathy.** Severe weakness, muscle stiffness, joint pain or nerve injuries can result of being immobile for long periods.

**Delirium is common.** Features include difficulty focusing, sudden changes in behaviour, confusion and paranoia but these get better, usually within days. The experience is distressing for you and your loved ones.

**Mental health problems,** such as anxiety, depression and post-traumatic stress disorder. If these problems were present before surgery, then they may get worse.

### Other early risks

**Severe allergic reactions** (anaphylaxis) to medications used at the time of surgery are very rare. Most patients recover completely.

**Difficulty swallowing.** This may require naso-gastric feeding to maintain nutrition during recovery.

**Sore throat or hoarse voice.** This may occur due to the breathing tube and TOE probe used at the time of surgery

**Eye abrasions.** Sedated patients do not blink, so the surface of the eye can become dry. If you are sedated for a long period, then your ICU nurse will lubricate your eyes regularly. In rare cases abrasions and infections can lead to vision loss.

**Pressure sores.** If you are not mobile, then the CCA team will reposition you on a regular basis to help prevent pressure sores. Specialized dressings are used to reduce the risk of skin injury by medical devices, such as the plastic tubes that are used in temporary MCS.

**Pancreatitis** (inflammation of the pancreas) can be serious or even fatal.

**Wound healing problems** that result in a painful or cosmetically disfiguring scar.

**Infection by a bacterium called Mycobacterium chimaera** can be associated with heart-lung bypass machines. The risk of infection is extremely small affecting approximately 1 in 10,000 patients. You will be offered a separate information leaflet about this problem.

### Long term risks

Adverse events may also occur after you have gone home, in the years after your LVAD has been implanted. These include:

**Infection** may occur around the driveline or the pump itself. Most driveline infections can be treated with antibiotic tablets. Deep-seated infections, or infections that are not responding to antibiotic tablets, may require treatment in hospital including intravenous antibiotics or an operation. It is very difficult to eradicate LVAD-associated infections and patients often require long-term antibiotic treatment to reduce the risk of the infection recurring. If the infection becomes resistant to treatment, then you may be prioritised for heart transplantation so the infected LVAD can be removed.

**Heart rhythm disturbances** are common in all patients with heart failure. Most heart rhythm disturbances do not affect patients with LVADs, but serious heart rhythm disturbances (such a ventricular tachycardia or ventricular fibrillation) may need urgent treatment with an electric shock. If you have recurrent VT or VF that we cannot control with medications or catheter ablation, then you may be prioritised for heart transplantation.

**Aortic regurgitation** occurs when the aortic valve (between the left ventricle and the aorta) starts to leak. This occurs in 8% of patients in the first two years of LVAD support. If aortic regurgitation is severe and your LVAD is not adequately supporting your circulation, then an operation may be necessary to replace the aortic valve. If aortic valve replacement is not possible, then you may be prioritised for heart transplantation.

**Right heart failure** occurs when the right ventricle struggles to cope with the demands of the implantable LVAD. Symptoms include fluid retention, rising requirement for diuretics such as furosemide and worsening kidney function. If you become dependent on intravenous medications (inotropes) to support your right ventricle, then you may be prioritised for heart transplantation.

**Anti HLA antibodies** may develop or increase in number after LVAD implantation. We call this sensitisation. It is more difficult to find a matching donor heart in the presence of significant sensitisation and you may wait longer for a heart transplant.

**Bleeding** from the gut or nose can occur. You may need a blood transfusion if there is significant blood loss. Some nose bleeds require ENT intervention such as packing or cauterisation. Bleeding from the gut will require endoscopic examination. Bleeding can be due to formation of fragile new blood vessels (angiodysplasia) in the gut. This is difficult to manage and may result in prioritisation for heart transplant. Repeated blood transfusions are associated with a risk of sensitisation.

**Outflow graft obstruction** is a problem with the pipe that connects the pump to your main aorta. If this pipe becomes twisted, kinked or compressed, your LVAD may not adequately support your circulation and an operation may be needed to fix the problem.

**Pump thrombosis** is a rare adverse event where blood clot forms within the pump. This can cause damage to blood passing through the pump (haemolysis), lead to stroke or cause the pump to stop completely. It is important to monitor data on your LVAD system controller because this can provide an early warning. Pump thrombosis is an emergency. Treatments include other types of anticoagulation or an operation to exchange the pump. If these treatments are not possible, then you may be prioritised for heart transplantation.

**Skin rashes** may occur in response to the dressing which fixes the driveline to your abdominal wall. We have an alternate dressing which may be better tolerated.

**Weight gain** is a common problem in patients with an LVAD. Excessive weight gain tends to lead to worsening symptoms. Weight gain is a risk factor for driveline infections. Weight gain may prevent you from receiving a heart transplant, particularly if your body mass index exceeds 35 kg/m2.

**Psychological problems** are common in patients with advanced heart failure, particularly those living with an LVAD. Please let us know if you are not feeling like your usual self or if your loved ones are worried about your mental health. We want to support you. We have a trained team of psychologists who work with our patients.

## What are the consequences of not having an implantable LVAD?

The alternative to having an implantable LVAD will vary between patients.

In simple terms, you would continue tablet treatment for heart failure. If there are no barriers to heart transplantation, then you might stay on the heart transplant waiting list. If there are barriers to heart transplant, then managing your condition would focus on treating symptoms and maximising quality of life. We would recommend involving our supportive and palliative care team who can help address physical, psychological, social and spiritual needs.

It is important to understand that the window of opportunity for an implantable LVAD may be short. If you delay having an implantable LVAD and there is deterioration in your right heart function, then you may no longer be suitable for an implantable LVAD.

If you decide not to proceed with an implantable LVAD, you do not have to sign the consent form. If you have signed a consent form, you have the right to withdraw your consent at any time before the time of the operation. If you decide that you no longer wish to continue implantable LVAD support after the pump has been implanted, then we would talk to you about withdrawal of mechanical circulatory support and palliative care.

## Further information

We hope that this information booklet has helped you understand implantable LVAD support. We understand that you may feel over-whelmed. Please know that we only recommend an implantable LVAD if we believe that the benefits outweigh the risks for you. Our team are here to talk through this information in detail and help you make your decision. Further information is available online:

mylvad.com/

pumpingmarvellous.org/heart-failure-guide/vads/

cardiovascular.abbott/us/en/hcp/products/heart-failure/left-ventricular-assist-devices/heartmate-3/patient-education.html

cardiovascular.abbott/us/en/patients/treatments-therapies/heartmate-lvad-therapy.html

gov.uk/transport/driving-and-medical-conditions

ics.ac.uk/Society/Patients_and_Relatives/A_Guide_to_ICU

rcoa.ac.uk/patient-information/patient-information-resources/anaesthesia-risk

nationalauditprojects.org.uk/downloads/PI-RISK08-AWARENESS-2015_0.pdf

## Contact Details

If you require any further assistance, our contact details are below:

Email: papworth.mcsd@nhs.net

Between 08:00 - 17:00 Monday to Friday
Call: 01223 638000 ask for bleep 235

Emergencies after hours / weekends
Call: 01223 638000

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## Alternative versions of this leaflet

Large print copies and alternative language versions of this leaflet can be made available on request.

View a digital version of this leaflet by scanning the QR code.

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As a member of Royal Papworth Hospital Foundation Trust, you could have your say on how the organisation is run, now and in the future. You will receive regular information and news from Royal Papworth and get invited to exclusive events. Membership allows you to vote for your representatives on the Council of Governors, talk to your Council of Governor representatives and stand as a governor.

Scan the QR code or head to royalpapworth.nhs.uk/our-hospital/how-we-are-run/foundation-trust-members to find out more.

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