Hartford HealthCare
Hartford Hospital

6816

INFORMED CONSENT FOR LEFT VENTRICULAR ASSIST DEVICE INSERTION

Patient Name: _____

I hereby authorize Dr._____to perform the following surgery and/or special procedure/treatment: LEFT VENTRICULAR ASSIST DEVICE INSERTION.

Additional procedures may include: ❑INTRA-AORTIC BALLOON PUMP REMOVAL
❑ AORTIC VALVE REPLACEMENT / REPAIR ❑ IMPELLA REMOVAL ❑ TRICUSPID VALVE REPAIR/REPLACEMENT
❑ EXTRACORPOREAL MEMBRANE OXYGENATION EXPLANT ❑ MITRAL VALVE REPAIR / REPLACEMENT

I understand that residents, medical students, physician assistants and/or advanced practice registered nurses may also be in attendance, and/or assisting in the performance, and/or performing significant medical/surgical tasks within the above specified surgery and/or special procedure/treatment. In addition, I understand that there may be unforeseen circumstances that are encountered while performing the above listed surgery /treatment that require the assistance of other qualified medical personnel who have not been identified.

In relation to the proposed surgery, I have had the following points explained to me: (i) the nature and purpose of the proposed surgery/treatment; (ii) the foreseeable risks and consequences of the proposed surgery/treatment, including the risk that the proposed surgery/treatment may not achieve the desired objective;
(iii) the alternatives to the proposed surgery/treatment and the associated risks and benefits to such alternatives; and (iv) the reasonably foreseeable risks and alternatives to the transfusion of blood and blood products should I need a blood transfusion. A discussion was held with me reviewing data regarding both national and center specific survival and quality of life benefit for left ventricular assist device implant.

Specifically, in obtaining my informed consent to the surgery /treatment, I have been informed of the following reasonably foreseeable risks:

- Death
- Need for reoperation
- High blood pressure
- Thromboembolism (blood clots that form and can travel to other parts of the body; this could result in a stroke or loss of a limb or organs and could require surgery)
- Prolonged ICU and/or hospital stay
- Psychiatric problems (disturbances in thought processes or emotions, behavioral changes)
- Infection (due to the device)
- Hemolysis (the destruction of blood cells)
- Heart attack
- Right heart failure (the right side of the heart is weak and fails to pump blood)
- Mechanical pump failure (the pump or its parts may stop working or malfunction)
- Arrhythmia (heart may beat irregularly or stop beating)
- Excessive bleeding
- Liver dysfunction (the liver fails to filter blood)
- Kidney Failure
- Need for mechanical ventilation (having a breathing tube and a machine to help you breathe)
- Neurological dysfunction (brain or nerve damage resulting in difficulty or inability to wake up or difficulty moving parts of the body)
- Pulmonary dysfunction (the lungs fail to oxygenate the body)

I understand that any of these complications may cause death.

I am aware that, in addition to the reasonably foreseeable risks described, there are other potential risks, which have been discussed with me, but are not listed. I affirm that I understand the purpose and potential benefits of the proposed treatment and/or special procedure, that no guarantee has been made to me as to the results that may be obtained, and that an offer has been made to me to answer any of my questions about the proposed surgery/treatment. I agree to the use of anesthesia and/or sedation/analgesia as required, and if applicable, the disposal of any tissue removed.

_____Patient Initial

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I acknowledge that pertinent data elements concerning my VAD implantation will be provided to the Interagency Registry of Mechanically Assisted Circulatory Support (INTERMACS). These data are collected primarily for quality control, as well as for regulatory considerations and reimbursement oversight. Access to this health information is highly restricted, and no published or unpublished report or presentation about the Registry will include any material that could identify me as a patient in the Registry.

I have been informed that I can expect discomfort after surgery similar to major heart surgery. I understand that I may also have some pain in the area around the tube site, which passes through the skin of the abdomen.

I also authorize the Hospital and the above-named physician(s) to photograph, video and /or use any other mediums which result in the permanent documentation of my image for medical, scientific or educational purposes, provided my identity is not revealed by them. I agree that any photographs taken pursuant to this authorization, which are not required by law to be retained, may be disposed of by the Hospital so long as the manner of disposition shall be permanent destruction.

This consent may be revocable by me at any time, except to the extent it has already been relied upon.

_____M. D. Signed: _____
(Patient or legally authorized representative)

Date:_____Time:_____ Date:_____Time:_____

Interpreter responsible for explaining procedures and special treatment:

_____(Interpreter)

Patient unable to sign prior to surgery [❒] because:

_____

_____M.D. Date:_____Time:_____

_____Witness Date:_____Time:_____