Hartford HealthCare

- ❑ Backus Hospital
- ❑ Charlotte Hungerford Hospital
- ❑ Hartford Hospital
- ❑ MidState Medical Center
- ❑ St. Vincent's Medical Center
- ❑ The Hospital of Central CT
- ❑ Windham Hospital

6816

Authorization for Acute Mechanical Circulatory Support Devices

Patient's Name: _____

Temporary Mechanical Circulatory Support Devices ("MCS") are used when the heart is not able to pump adequately to provide enough nutrients and oxygen to other organs in the body. I understand I am being consented for implant of a MCS device such as:

Definitions:
Intra-aortic Heart Pump: is a heart pump implanted under your skin (through an artery in your groin or shoulder area) that uses a balloon to assist in pumping blood to your body.

Impella Heart Pump: is a heart pump that is implanted under your skin (through an artery or vein in your groin or axillary area) that uses an impeller to assist in pumping blood from the heart for patients with heart failure.

Extracorporeal Membrane Oxygenation (ECMO): is a heart and/or lung pump that is implanted under your skin (through an artery or vein in your groin or shoulder area) as acute circulatory support in patients with cardiac and/or respiratory failure, and has the capability of assisting with cardiac output for organ function and simultaneous gas exchange for acute cardiorespiratory failure. The machine is external to my body, with certain catheters inserted near or in my heart.

Acute MCS devices are treatment options for patients in need of temporary support devices due to severe heart failure or inadequate blood flow to the heart such as after a heart attack, during a high-risk cardiac procedure, after a severe infection or awaiting heart transplant. These devices as noted above can improve the amount of blood that that heart is able to pump.

I hereby authorize Dr._____ to perform the following special procedure or treatment:

_____

I understand that perfusionists, medical education residents, medical students, physician assistants, Emergency Medical Service Personnel (EMS) and advanced practice registered nurses may be in attendance, assisting in the performance, and/or performing significant medical/surgical tasks within the above specified special procedure/treatment. In addition, I understand that there may be unforeseen circumstances that are encountered while performing the above listed and/or special procedure/treatment that require the assistance of other qualified medical personnel who have not been identified. I am also aware that vendor representation may be present in an observational role only.

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I have had explained to me in connection with the proposed procedure/treatment:

(i) The nature and purpose of the proposed procedure/treatment
(ii) The foreseeable risks and consequences of the proposed procedure/treatment, including the risk that the proposed procedure/treatment may not achieve the desired objective
(iii) The alternatives to the proposed procedure/treatment and the associated risks and benefits to such alternatives
(iv) The reasonably foreseeable risks and alternatives to the transfusion of blood and blood products should I need a blood transfusion
(v) That many temporary MCS systems are often used in clinical practice for longer than on-label indication and this may be the case with me.

Specifically, in obtaining my informed consent to the use of the above MCS devices, I have been informed of the following reasonably foreseeable risks:

<table>
<tr><td>• Death</td><td>• Stroke</td><td>• Bleeding</td><td>• Infection</td></tr>
<tr><td>• Arrhythmia</td><td>• Cardiac Thrombus (blood clot in the heart)
• Bleeding</td><td>• Neuropathy/Paresthesia (numbness and tingling of extremities)</td><td>• Carotid Artery Injury</td></tr>
<tr><td>• Heart Attack/Failure</td><td>• Kidney problems</td><td>• Lung problems</td><td>• Liver problems</td></tr>
<tr><td rowspan="2">• Distal extremity infection or ischemia</td><td colspan="2">• Trash foot syndrome (artery damage to feet)</td><td rowspan="2">• Compartment Syndrome</td></tr>
<tr><td colspan="2">• Purge solution leak if a purge solution is required</td></tr>
<tr><td colspan="2">• Bowel ischemia (decreased blood flow to bowels)</td><td colspan="2">• Cannula dislodgement that would lead to massive bleeding</td></tr>
</table>

I also understand that access cannulas and catheters, when used for greater than 6 hours or for ECMO/temporary mechanical circulatory support may pose a risk of significant blood loss, vascular complication, infection/risk of infection (such as loss of protective sheath integrity) and/or death.

I also understand that with use of MCS, once treatment has begun that I will continue to be monitored with invasive and noninvasive monitoring, and further, that in the event that discontinuation of MCS is recommended or I desire the MCS device to be discontinued and the risks and benefits are discussed, it will be done through a weaning process to determine whether discontinuation may be tolerated by me. I understand that if I request acute discontinuation of an MCS device, which this may result in my death.

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I understand that in using MCS devices that I will likely receive certain medications to support use of the MCS device, including but not limited to anticoagulation medications. While there is no guarantee as to how long the MCS device will be used, I have been provided an estimate of the desired time period.

I am aware that, in addition to the reasonably foreseeable risks described, there are other foreseeable risks, which have been discussed with me, but are not listed. I affirm that I understand the purpose and potential risks/benefits of the proposed treatment and/or special procedure. I acknowledge that no guarantee is made as to the results of this procedure and that an I was given an opportunity to ask questions about the proposed procedure/treatment with adequate time for responses.

I agree to the use of anesthesia and/or sedation/analgesia as required, and if applicable, the disposal of any tissue removed.

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.

I have carefully read and fully understand this informed consent form, and have had sufficient opportunity to discuss my condition and the above procedure(s) with the care provider and his/her associates, and all of my questions have been answered to my satisfaction. This consent may be revocable by me at any time, except to the extent it has already been relied upon.

This consent may be revocable by me at any time, except to the extent it has already been relied upon. Notwithstanding, prior to honoring the revocation, I understand that the hospital ethics committee may be consulted.

_____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:_____