

- Inpatient
- Outpatient
- ED

**CONSENT FOR
DEVICE IMPLANT**

SH 419ICD MR

Page 1 of 2

Patient Name: _____ DOB: _____

I hereby give my consent and authorize

(The list of possible assistants, all of whom are credentialed to provide surgical services at the hospital, is available)

to treat the following conditions:

Abnormal heart rhythm(s), congestive heart failure, syncope or fainting.

by performing the following procedure(s):

To implant or revise, replace or remove a pacemaker, defibrillator (ICD) or loop recorder. After anesthesia or intravenous sedation and sterile preparation, one or more incisions will be made and a pocket created or revised for the pacemaker, ICD or loop recorder under the skin. One or more pacemaker or ICD leads may be positioned or removed from the heart. X-ray (fluoroscopy), ultrasound, contrast dye, and cardioversion of abnormal heart rhythms may be used. The device battery will require replacement eventually.

1. The care provider has explained my condition to me, the benefits of having the above treatment procedure, and alternate ways of treating my condition. I understand that no guarantees have been made to me about the result of the treatment. The alternatives to this procedure include:
Not performing the procedure.
2. The care provider has discussed with me the reasonably foreseeable risks of the treatment and that there may be undesirable results. The risks that are specifically related to this procedure include:
Bleeding or bruising at implant sites; infection or erosion through the skin (possibly requiring removal of the device and leads); bleeding around the heart (cardiac tamponade); injury to blood vessels, heart valves or other organs; pneumothorax (collapsed lung); possible need for elective or emergent surgery or procedure to repair an injury; possible need for re-operation due to lead dislodgment or other abnormality of the device system; irregular heart rhythms which could require cardioversion shock, blood clot, allergic reactions; respiratory (breathing) depression which could require assisted breathing with a respirator (breathing machine) x-ray induced skin injury or other risks; possible need for blood transfusion; stroke; myocardial infarction; or death.
3. I understand that during the treatment a condition may be discovered which was not known about before the treatment started. Therefore, I authorize the care provider to perform any additional or different treatment which is thought necessary and available.
4. I consent to the administration of local, regional or general anesthesia and/or sedation as deemed most appropriate for the procedure to be performed. (The list of possible anesthesia providers, all of whom are credentialed to provide anesthesia at this hospital, is available).
5. Any tissue, parts, or substances removed during the procedure may be retained or disposed of in accordance with customary scientific, educational and clinical practice.
6. At the discretion of the doctor I consent to the presence of manufacturer's representatives to aid in the service and correct calibration of the correct instrumentation. I understand that at no time will these representatives actively participate in my procedure.

RR DONNELLEY

SMH-Consents
HH-Consents

**CONSENT FOR
DEVICE IMPLANT**

SH 419ICD MR

Page 2 of 2

Patient Name: _____ DOB: _____

7. **Patient Consent for Medical or Surgical Procedure: 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.**

Patient
Sign here →

_____	_____	_____
Signature of Patient	Date	Time
_____	_____	
Signature of Parent or Legal Guardian (if Patient is unable to sign or is a minor)	Relationship to the Patient	

Complete this section for all OR procedures and all other invasive internal procedures performed in any setting.

8. **Consent for Receipt of Tissue(s):**

- yes (please list), _____
 not expected to be needed, but may be required and given in an emergency
 refused
 n/a

9. **Consent for Blood Transfusion:**

- yes
 not expected to be needed, but may be required and given in an emergency
 refused. Refer to SMH Policy 9.18 (Refusal of Blood (or Blood Products) Transfusions or HH Policy 4.1 (Blood Transfusion-Refusal to Permit).
 n/a

For those procedures that have the potential for significant blood loss, I consent to the transfusion of blood or blood components that may be necessary before, during or after the procedure. I have been informed that no transfusion is 100% safe, however present testing methods make the risks of infection very small. Risks include infection from viruses, bacteria, or parasites, including but not limited to HIV (the AIDS virus) and hepatitis, as well as fever, chills, allergy, volume overload, or death. I have discussed possible alternatives with my care provider, including no transfusion, autologous transfusion (donation of my own blood), designated/directed donor transfusion (collection of blood from donors selected by me) or blood salvage during the procedure. I understand that these alternatives may not be available due to timing or health reasons, and the above risks may still apply.

10. **Patient Consent for Blood/Tissue: I have had a chance to discuss the risks, benefits and alternatives regarding transfusion/receipt of tissue (as above) with my healthcare provider. My decision(s) regarding the transfusion of blood or blood components and/or the receipt of tissue are as above. I understand this covers my perioperative/peri-procedural (before, during, and after the surgery/procedure) course of treatment.**

Patient sign
here unless
8 and 9 n/a

_____	_____	_____
Signature of Patient	Date	Time
_____	_____	
Signature of Parent or Legal Guardian (if Patient is unable to sign or is a minor)	Relationship to the Patient	

ATTESTATION

I have discussed the planned procedure, including the potential for any transfusion of blood products or receipt of tissue as necessary, expected benefits, the potential complications and risks and possible alternatives and their benefits and risks with the patient or the patient's surrogate. In my opinion, the patient or the patient's surrogate understands the proposed procedure, its risks, benefits, and alternatives.

Provider
Sign here →

_____	_____	_____
Signature of Care Provider	Date	Time
_____	_____	
Printed name and title		