Cardiovascular Medicine
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ICANL Nuclear Cardiology Accredited Nuclear Cardiology Laboratory

International Board of Heart Rhythm Examiners
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Physician

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INFORMED CONSENT FOR IMPLANTED CARDIAC MONITOR

(Implantable Loop Recorder / Insertable Cardiac Monitor)

Patient Name | Date of Birth | Date

Indication / Diagnosis | Device / Model (if known)

Reason for Monitoring: ☐ Syncope / near-syncope ☐ Palpitations ☐ Atrial fibrillation surveillance
☐ Cryptogenic stroke / TIA ☐ Other:

PURPOSE OF THE PROCEDURE

My physician has recommended an implanted cardiac monitor (also called an implantable loop recorder or insertable cardiac monitor) to continuously monitor my heart rhythm for abnormal rhythms that may occur intermittently and may not be detected by shorter external monitoring. The device can store automatically detected events and, depending on the system, patient-activated recordings.

DESCRIPTION OF THE PROCEDURE

The procedure is usually performed with local anesthetic. A small incision or puncture is made in the upper chest, and the monitor is placed under the skin. The incision is then closed with adhesive, sutures, strips, or another dressing method. The device does not contain leads that enter the heart. The implant typically remains in place until adequate diagnostic information is obtained, the battery reaches end of service, or removal is otherwise recommended.

REMOTE MONITORING AND DATA TRANSMISSION

The implanted monitor may communicate with a home transmitter, smartphone, or other remote-monitoring system. Rhythm recordings and device information may be transmitted to my medical team. I understand that remote monitoring is not an emergency response system, transmission may be delayed or fail, and urgent symptoms require appropriate emergency evaluation rather than reliance on the monitor.

☐ I understand and agree to remote monitoring/data transmission when prescribed.

EXPECTED BENEFITS

Potential benefits include improved detection and documentation of intermittent arrhythmias, correlation of symptoms with heart rhythm, and information that may help guide diagnosis and treatment. The procedure may not identify the cause of my symptoms, and no specific diagnostic or treatment outcome is guaranteed.

RISKS AND POSSIBLE COMPLICATIONS

- Pain, tenderness, bruising, swelling, bleeding, or hematoma at the implant site.
- Infection, wound drainage, delayed healing, skin irritation, scarring, or keloid formation.
- Allergic or adverse reaction to local anesthetic, antiseptic, adhesive, dressing materials, or device components.
- Numbness, tingling, local nerve irritation, or persistent discomfort at the implant site.
- Device movement, migration, rotation, erosion through the skin, extrusion, or local tissue reaction.
- Failure of the device to sense or record an arrhythmia; false or inappropriate detections; inaccurate or incomplete recordings.
- Failure or delay of remote transmission, smartphone/app communication, or home-monitor connectivity.
- Premature battery depletion, device malfunction, or need for reprogramming, repositioning, removal, or replacement.
- Need for antibiotics, additional testing, an additional procedure, or hospitalization if a complication occurs.
- Rare or unforeseen complications can occur despite appropriate technique.

MRI / ELECTROMAGNETIC AND DEVICE PRECAUTIONS

Many implanted cardiac monitors are MRI-conditional, but MRI safety depends on the exact device and manufacturer conditions. I will inform healthcare professionals that I have an implanted cardiac monitor before MRI or other procedures involving strong electromagnetic fields. I will follow the manufacturer's device-specific precautions and carry device identification information when provided.

ALTERNATIVES

Depending on my condition, alternatives may include no monitoring at this time, office electrocardiograms, Holter monitoring, patch monitoring, external event monitoring, mobile cardiac telemetry, consumer/wearable rhythm monitoring, or other diagnostic testing. External monitors generally provide a shorter monitoring period and may be less likely to capture infrequent events.

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AFTER THE PROCEDURE

I will follow wound-care and activity instructions. I understand that I should contact my medical team for increasing redness, swelling, drainage, fever, worsening pain, opening of the incision, device protrusion, or other concerning symptoms. Chest pain, severe shortness of breath, fainting, stroke-like symptoms, or other possible emergencies require urgent medical evaluation.

PATIENT ACKNOWLEDGMENT AND CONSENT

I have had the nature and purpose of the implanted cardiac monitor procedure, expected benefits, risks, possible complications, alternatives, remote-monitoring considerations, and consequences of declining the procedure explained to me. I understand that medicine is not an exact science and no guarantee has been made regarding diagnosis or outcome. I have informed my healthcare team about allergies, medications, bleeding problems, infections, implanted devices, and other relevant medical information. I have had the opportunity to ask questions, and my questions have been answered to my satisfaction. I voluntarily authorize my physician and appropriate clinical personnel to perform the implanted cardiac monitor procedure described above.

ADDITIONAL COMMENTS / PATIENT QUESTIONS

SIGNATURES

Patient / Authorized Representative Signature (type name if electronically signing)

Date / Time

Printed Name

Relationship to Patient (if applicable)

Physician / Qualified Clinician Signature (type name if electronically signing)

Date / Time

Witness Signature (type name if electronically signing)

Date / Time

Practice / Facility

Medical Record # (optional)

Practice template: Review and adapt this form to applicable law, institutional policy, current device-specific manufacturer labeling, and the patient's individual circumstances before clinical use.