



PERMANENT PACEMAKER IMPLANTATION CARDIOVERTER / DEFIBRILLATOR IMPLANTATION

The purpose of this document is to provide written information regarding the risks, benefits and alternatives of the procedure named above. This material serves as a supplement to the discussion you have with your physician. It is important that you fully understand this information, so please read this document thoroughly.

The Procedure: *Permanent pacemaker* implantation keeps the heart from beating too slowly. A battery is implanted under the skin. One or two thin coated “wires” are inserted in the heart through a vein and attached to the battery. *Cardioverter / defibrillator* implantation recognizes and corrects certain abnormal heart rhythms by one of the following methods: (1) May shock the heart one or more times or (2) May stimulate the heart at very fast intervals.

Benefits

If your implantation is successful, you might receive the following benefits. The doctors cannot guarantee you will receive any of these benefits. The doctors cannot guarantee that you will live longer than if you had not had an implantation. Only you can decide if the potential benefits are worth the risks.

1. With a properly functioning pacemaker, you will no longer be at risk for potential episodes of a slow heart rate.
2. A properly functioning cardioverter / defibrillator can protect you against the potential for life threatening cardiac arrhythmias.
3. However, you should not expect any damage which has already occurred to get better after the implantation has been completed.

Risks

Implantation of a pacemaker or cardioverter / defibrillator is an important procedure and doctors cannot guarantee that the implant will be successful for you. No procedure is completely risk-free. It is a well established procedure and in general quite safe; however, there are remote risks of serious life-threatening complications during and after the procedure. The following risks are well recognized, but there may also be

risks not included in this list that are unforeseen by your doctors.

Permanent Pacemaker Implantation:

1. You may experience adverse reactions to medications used during the procedure.
2. You may have a heart attack that may be life-threatening and can cause life-long disability.

3. Air may leak into the chest cavity causing the lung to collapse and creating a pneumothorax. Placement of a chest tube may be required.
4. The procedure may result in lead dislodgment requiring repositioning.
5. Placement may dislodge a clot that could travel to a distant organ or brain and cause a stroke.
6. The procedure could initiate a dangerous cardiac rhythm requiring external shock(s).
7. Hematoma (bleeding under the skin) may develop at the incision site.
8. Placement could result in cardiac perforation. In this complication, blood leaks into the sac around the heart and compromises the heart's pumping action. A needle under the breast bone is used to remove the blood (pericardiocentesis).
9. The procedure could result in bleeding and/or blood vessel damage requiring repair. Separate information is available regarding blood transfusion, products, and alternatives.
10. You may die during the operation.

Cardioverter / Defibrillator Implantation:

1. You may experience adverse reactions to medications used during the procedure.

2. You may have a heart attack that may be life-threatening and can cause life-long disability.
3. Air may leak into the chest cavity causing the lung to collapse and creating a pneumothorax. Placement of a chest tube may be required.
4. The procedure may result in lead dislodgment requiring repositioning.
5. Placement may dislodge a clot that could travel to the brain and cause a stroke.
6. The procedure could initiate a dangerous cardiac rhythm requiring external shock(s).
7. Hematoma (bleeding under the skin) may develop at the incision site.
8. Placement could result in cardiac perforation. In this complication, blood leaks into the sac around the heart and compromises the heart's pumping action. A needle under the breast bone is used to remove the blood (pericardiocentesis).
9. The procedure could result in bleeding and/or blood vessel damage requiring repair. Separate information is available regarding blood transfusion, products, and alternatives.
10. You may experience inappropriate shocks
11. Inability to terminate the abnormal rhythm.
12. You may die during the operation.

Alternatives

The alternative to getting a pacemaker or cardioverter / defibrillator implant is to not have the

implant. If you decide against this, you may be eligible for a drug regimen for your symptoms.

If you have any questions regarding the procedure, risks, benefits, or alternatives to this procedure please ask your physician prior to signing any consent forms.



Patient Signature

Date