



ADDITION OF A CORONARY SINUS LEAD TO AN EXISTING PERMANENT PACEMAKER OR ICD SYSTEM

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 or ICD implantation involves the insertion of a single heart lead (wire) into the right ventricle. When a pacing stimulus is delivered through this lead, both ventricles are stimulated. However the right ventricle contracts slightly earlier than the left. The addition of a coronary sinus lead attempts to have both ventricles contract simultaneously in a manner that would occur during normal cardiac function. In other words, the normal heart will stimulate both ventricles at the same time. This type of therapy is referred to as **biventricular pacing**.

Benefits

If your implantation is successful, you might receive the following benefits. The doctors cannot guarantee you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

1. With a properly functioning **biventricular pacemaker** or **ICD**, the pumping action of your heart may improve and you may experience a greater sense of well-being.
2. Your tolerance to the activities of daily (ADL) may also improve.

Risks

Before undergoing this procedure, understanding the associated risks is essential. No procedure is completely risk free.

The following risks are well recognized, but there may also be risks not included in this list that are unforeseen by your doctors.

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

2. You may have a heart attack that may be life-threatening and cause life-long disability.
3. Air may leak into the chest cavity causing the lung to collapse (pneumothorax) which may require placement of a chest tube and extend your hospital stay.
4. The procedure may result in lead dislodgement that may require repositioning or **removal** of the atrial lead.

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| <ol style="list-style-type: none"> 5. Placement of the lead 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 result at the incision site. 8. Lead placement could result in cardiac perforation, where 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, also called pericardiocentesis. 9. There could be bleeding or blood vessel damage requiring repair, surgery, or blood replacement. 10. Lead placement will require the use of one or more contrast injections which could cause a severe life-threatening allergic reaction or kidney injection. 11. Your anatomy may not accept the coronary sinus lead which will have to be removed, leaving you with the same therapy you presently have. | <ol style="list-style-type: none"> 12. The coronary sinus lead may fail to provide biventricular pacing. 13. The coronary sinus lead may cause a blocked blood vessel. 14. The coronary sinus lead, or any pacing lead, may fracture, resulting in loss of pacing function. 15. Your symptoms may not improve after the implantation has been completed. Any one of the leads may damage a blood vessel or the coronary sinus, which could require immediate surgical repair with open heart surgery. 16. You may develop an infection which would require a course of antibiotics and an increase in your hospital stay. 17. You may die during the procedure. 18. If a coronary sinus lead has been successfully placed, your existing ICD or pacemaker will be replaced with a biventricular model. 19. Pain may be associated with this procedure and the healing process. |
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Alternatives

The alternatives include:

1. Not having the procedure.
2. A medication regimen.

If you decide not to have this procedure, there are associated risks to this decision.

Please discuss it with your doctor.

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



Patient Signature

Date