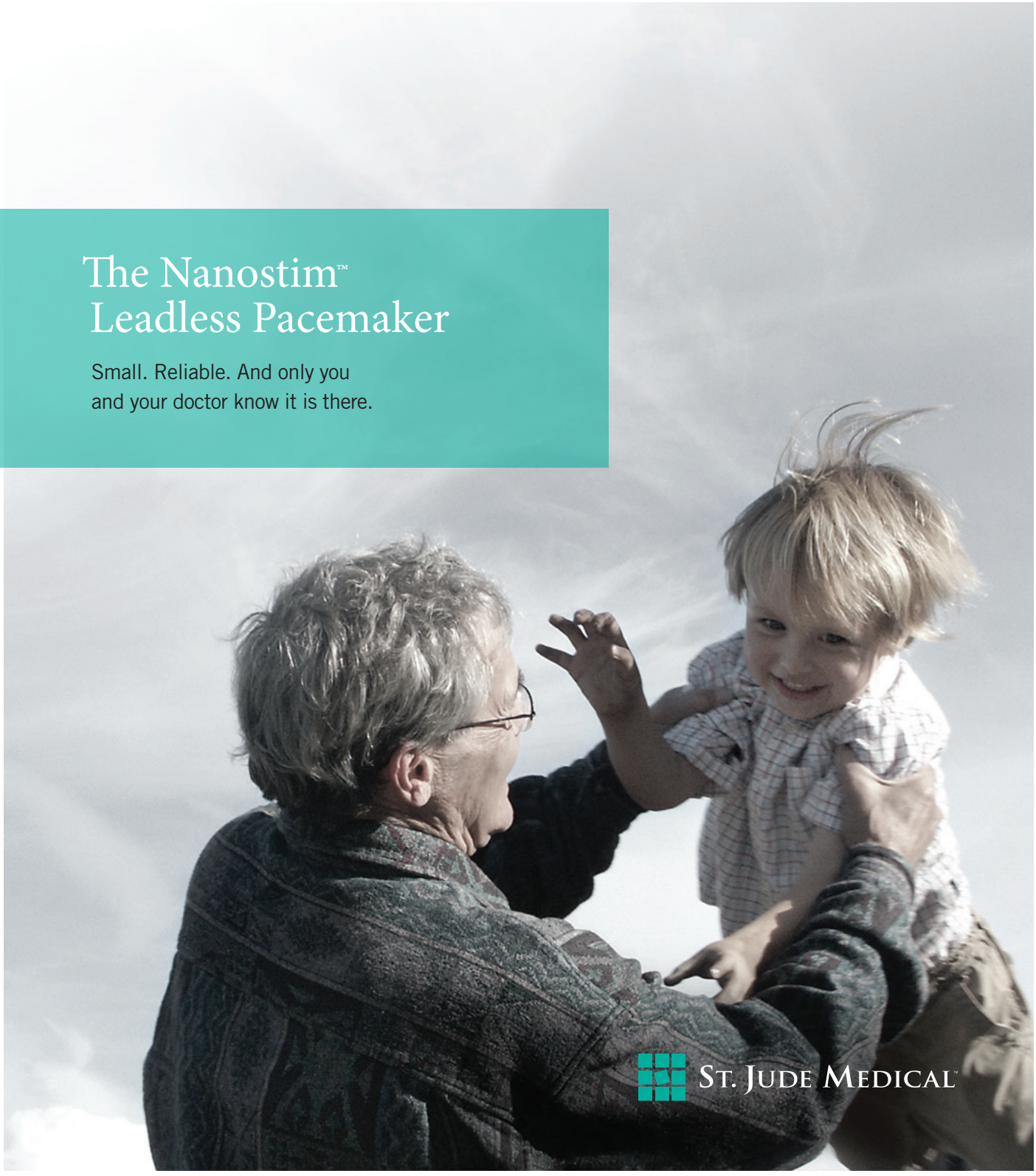
The Nanostim™ Leadless Pacemaker

Small. Reliable. And only you
and your doctor know it is there.



ST. JUDE MEDICAL™

INTRODUCING THE

Nanostim™ Leadless Pacemaker

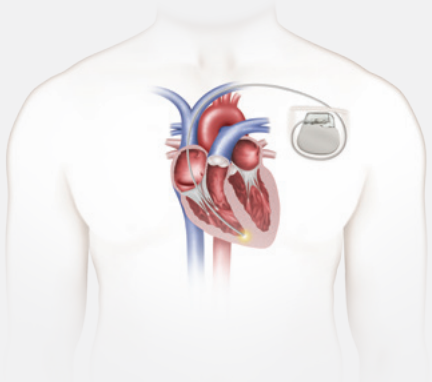
While standard pacemakers can improve a patient's quality of life and may even prolong it, physicians and patients have long asked for a pacemaker that does not require an unsightly surgical pocket that may restrict a patient's mobility or become infected. They also want a solution that eliminates leads, which in rare cases may fail or dislodge.

St Jude Medical, the company that invented the world's first implantable pacemaker in 1958, is proud to introduce the Nanostim™ leadless pacemaker, the world's first commercially available and self-contained leadless pacemaker.

This small cylindrical pacemaker is smaller than a AAA battery, and it listens to the electrical activity of the heart, stimulates if necessary and communicates to a programming system, like a standard pacemaker. But, unlike standard pacemakers, it resides entirely in the right ventricle of your heart. This pacemaker requires no leads, no chest incision, no scar and no permanent lump under the skin where the pacemaker sits. The pacemaker battery life is equivalent to that of similar standard single chamber pacemakers.

Traditional Pacemakers

A normal, healthy heart automatically regulates its own heart rate. Unfortunately, some hearts beat too slowly or in an irregular pattern. If you are diagnosed with this problem, your doctor may recommend a pacemaker to correct it.



Traditional single chamber pacemakers require your doctor to make a surgical incision in the chest where a pacemaker permanently sits in a pocket under your skin. The doctor then implants thin insulated wires – which are called leads - from the pacemaker through the veins into your heart. These leads deliver electrical pulses that prompt your heart to beat at a normal rate.

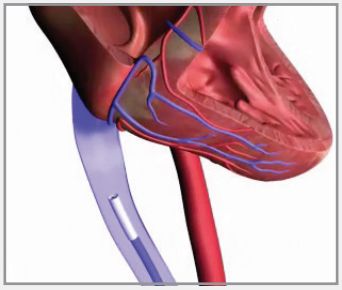
Understand traditional pacemaker complication risks

More than four million people around the world have an implanted pacemaker or other cardiac rhythm management device, and more than 700,000 additional patients receive an implant every year. Although the incidence of pacemaker complications is relatively low (about 4%[1,2,3]), when complications occur, they typically happen in the pocket where the pacemaker is implanted or with the leads. In about 1%[4,5] of patients, the pocket may become infected. In about 3%[1,6] of patients, the leads may move out of place causing complications.

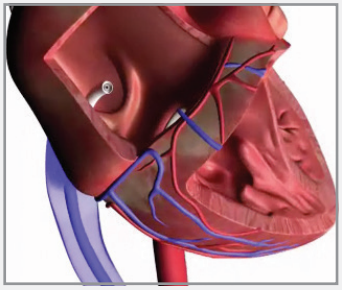
While rare, complications can have a serious impact on a patient's quality of life and also can be expensive to address. Even if complications do not occur, all patients have a scar and lump where pacemaker is implanted. In addition, research has shown that as many as six out of 10 patients experience reduced mobility in the shoulder region where the pacemaker is implanted.[7] With the Nanostim leadless pacemaker, the surgical pocket and leads are eliminated, which means reducing the risks associated with these complications.

What to expect when you have the Nanostim leadless pacemaker implanted

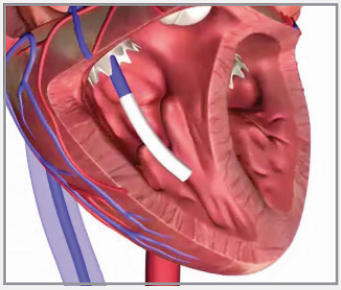
To place this pacemaker, your doctor performs a minimally invasive procedure using X-ray images as a guide. A catheter that contains the pacemaker is passed through a small puncture in the groin and threaded into the heart. Once inside the heart, your doctor will attach the Nanostim leadless pacemaker to the wall of your heart near the bottom of the right ventricle and then gently remove the catheter from your vein. If necessary, the pacemaker can be repositioned or even removed at a later time. When the pacemaker needs to be replaced, (typically after eight years or longer), your doctor implants it the same way.



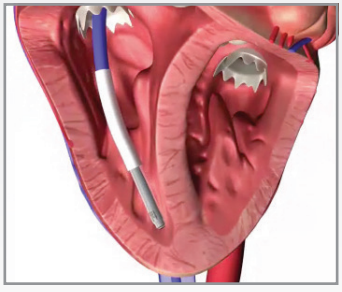
A catheter that contains the leadless pacemaker is passed through a small puncture in the groin and then into the femoral vein.



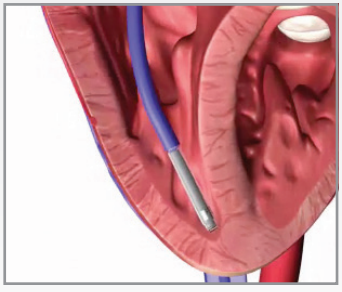
Using X-ray images as a guide, the doctor guides the catheter to the right atrium of the heart and through the tricuspid valve.



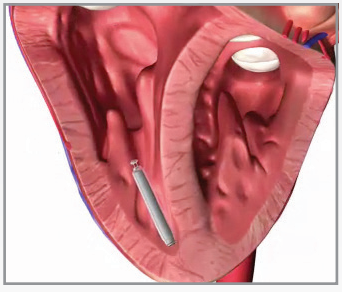
The catheter with the pacemaker is then guided into the right ventricle.



The doctor carefully places the pacemaker and secures it to the wall at the bottom of the right ventricle.



The pacemaker is then tested to ensure it is secured to the wall and programmed correctly.



The catheter is removed and the pacemaker stays within the right ventricle.

For most people, the procedure is done under local anesthetic. You will be given some medicine to calm you and numbing medicine for your upper leg. The actual procedure will take about one hour, and in some cases less time. When it is over, you will have a special closing bandage on your groin, and you may have to wait in a recovery room until the clinical team is certain you are ready for discharge.

After you first receive the Nanostim leadless pacemaker, you will be asked to see your doctor a few times. During these visits, he or she will check that you are recovering well and that Nanostim leadless pacemaker is operating properly. The pacemaker can be adjusted by your doctor using a programmer that communicates with the implanted leadless pacemaker. This adjustment is completely painless and takes a few minutes. Your doctor might adjust your pacemaker to pace your heart faster or slower or to deliver slightly more or slightly less energy. Over time, your doctor may have to make several adjustments so that you receive optimal therapy for your condition.

Understand the Risks of the Nanostim Leadless Pacemaker

The general risks of the procedure include: severe bleeding or bruising; infections, including infections of the heart or surrounding tissues; infections or other complications of the blood or wounds; allergies and intolerance reactions; dizziness; shortness of breath; chest pain or heart problems; heart attack; irritability or damage to your heart; heart rhythm changes; rupture of a blood vessel; the formation of blood clots; air or debris traveling in your blood to your brain, heart, or lungs; emergency surgery; excess fluid in your vessels or lungs that affect your kidneys; kidney failure; complications from anesthesia or other medication; blood pressure problems; pain; minor or major stroke; death; damage to skin, blood vessels, soft tissue, or nerves; excessive scar formation; and compression damage to nerves and soft tissues.

Talk with your doctor to understand the potential risks and benefits of this therapy.

> To learn more about the Nanostim leadless pacemaker, visit www.leadlesspacing.com

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