

# Leadless Pacemaker

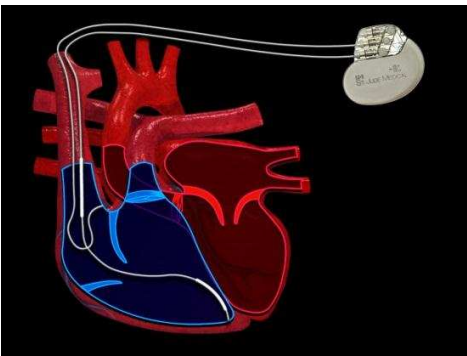
## Fact Sheet

### WHAT IS A LEADLESS PACEMAKER?

A leadless pacemaker is a small implantable device that sends electrical pulses to the heart whenever it senses that the heartbeat is too slow. Leadless pacing devices are placed directly in the heart without the need for a surgical pocket and insulated wires (called leads).

### HOW DOES A CONVENTIONAL PACEMAKER WORK?

Conventional pacemakers work as part of a pacing system that consists of a pulse generator and pacing leads.



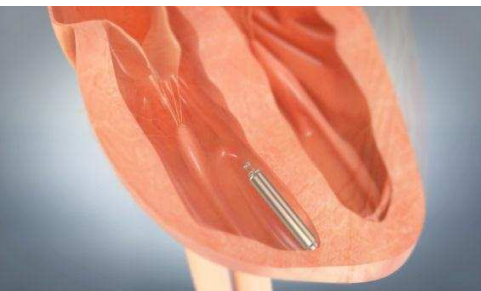
**Pulse generator:** a device implanted just below the skin near the collarbone. The pulse generator contains the battery and the electronic circuitry, or brain of the pacemaker, which directs the battery to send electrical pulses to the heart.

**Leads:** thin wires that are inserted through a vein, which connect the generator to the heart. The leads also pick up the patient's own heart rhythm and transmit this information to the generator, which adapts its responses to the patient's needs.

Conventional pacemakers require the doctor to make a surgical incision in the chest where a pacemaker permanently sits in a pocket under the skin. The doctor then implants leads from the pacemaker through the veins into the heart. These leads deliver electrical pulses that prompt the heart to beat at a normal rate.

### HOW DOES A LEADLESS PACEMAKER WORK?

Unlike conventional pacemakers, a leadless pacemaker is placed directly in the heart without the need for a surgical pocket and pacing leads. The device is much smaller than a conventional pacemaker and is comprised of a pulse generator that includes a battery and a steroid-eluting electrode that sends pulses to the heart when it recognizes a problem with the heart's rhythm.



Leadless pacemaker technology is made up of computer chips and a small, but long-lived battery in a sealed case that resembles a AAA battery. The device is implanted through a vein that passes fairly close to the outer surface of the upper thighs. Because the implant procedure does not require surgery like a traditional procedure, it is considered a less-invasive approach for patients who need pacemaker technology.

### WHO NEEDS A PACEMAKER?

A pacemaker is prescribed when a heart's electrical conduction system malfunctions and causes the heart to beat too slowly (called bradycardia). Sometimes a dangerously slow rhythm is discovered during a routine checkup without the patient being aware of a problem (indicating that the condition developed slowly and enabled the body to adapt).

St. Jude Medical, Inc.  
Global Headquarters  
One St. Jude Medical Drive  
St. Paul, MN 55117

[sjm.com](http://sjm.com)

### Media Contact

Kate Stoltenberg  
Tel: 651-756-3388  
[kstoltenberg@sjm.com](mailto:kstoltenberg@sjm.com)

Symptoms, when present, vary significantly. They often include lightheadedness, shortness of breath, fatigue, weakness, fainting or near-fainting spells, and an inability to participate in heavy physical activity. While symptoms may be due to many different causes, pacing is indicated only when symptoms are caused by a persistent or intermittently slow heart rhythm.

### Fast Fact

More than four million people worldwide have an implanted pacemaker or other cardiac rhythm management device, and an additional 700,000 patients receive the devices each year

### HOW DO PHYSICIANS DETERMINE WHETHER A PATIENT NEEDS A PACEMAKER?

To determine whether a pacemaker is needed, doctors administer an electrocardiogram (ECG) that provides a graphic representation of the heart's rhythm. Often, a recording of the heart rhythm is taken over many hours to catch infrequent symptomatic episodes.

### HOW IS NANOSTIM LEADLESS TECHNOLOGY UNIQUE?

St. Jude Medical is at the forefront of developing transformative medical solutions that are changing the way that medicine is practiced around the world. Nanostim™ is the world's first and only commercially available leadless pacemaker.



The Nanostim leadless pacemaker offers patients a minimally-invasive option for pacemaker delivery. Implanted via the femoral vein with a steerable catheter, the device offers a less-invasive approach that eliminates the surgical pocket and lead, potentially reducing overall complications such as device-related infection of the pocket and lead failure.

The Nanostim leadless pacemaker is less than 10 percent the size of a conventional pacemaker. The small size of the device, coupled with the lack of a surgical pocket, improves patient comfort. In addition, the removal of patient activity restrictions that may prevent the dislodgement of a conventional lead may potentially improve the quality of life for patients with this technology.

The Nanostim leadless pacemaker will soon be available in select European markets and is not approved for sale in the U.S.

St. Jude Medical, Inc.  
Global Headquarters  
One St. Jude Medical Drive  
St. Paul, MN 55117

[sjm.com](http://sjm.com)

Caution: Investigational Device Limited by Federal (or United States) Law to Investigational Use. Not Approved for Sale in the U.S.