Nanostim™ Leadless Pacemaker for Cardiac Arrhythmias

Caution: Investigational device. Limited by federal United States law to investigational use only.

More than 4 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, when complications occur, they typically happen in the pocket where the pacemaker is implanted or with the leads. 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 the pacemaker is implanted.

Unlike conventional pacemakers that require a more invasive surgery, the Nanostim leadless pacemaker is designed to be implanted directly into the heart via a minimally invasive procedure. The device is delivered using a steerable catheter through the femoral vein, eliminating the need to surgically create a pocket for the pacemaker and insulated wires (called leads) that have historically been recognized as the most vulnerable component of pacing systems.

Contact Us for More Information

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Inclusion Criteria

- Subject must have one of the clinical indications in adherence with Medicare, ACC/AHA/HRS/ESC single chamber pacing guidelines including:
  - Chronic and/or permanent atrial fibrillation with 2 or 3° AV or bifascicular bundle branch block (BBB block), including slow ventricular rates (with or without medication) associated with atrial fibrillation; or
  - Normal sinus rhythm with 2 or 3° AV or BBB block and a low level of physical activity or short expected lifespan (but at least one year); or
  - Sinus bradycardia with infrequent pauses or unexplained syncope with EP findings; and
- Subject ≥18 years of age; and
- Subject has life expectancy of at least one year; and
- Subject is not enrolled in another clinical investigation; and
- Subject is willing to comply with clinical investigation procedures and agrees to return for all required follow-up visits, tests and exams; and
- Subject has been informed of the nature of the study, agrees to its provisions and has provided written informed consent, approved by the IRB; and
- Subject is not pregnant and does not plan to get pregnant during the course of the study

Exclusion Criteria

- Subject has pacemaker syndrome, has retrograde VA conduction or suffers a drop in arterial blood pressure with the onset of ventricular pacing; or
- Subject is allergic or hypersensitive to <1 mg of dexamethasone sodium phosphate; or
- Subject has a mechanical tricuspid valve prosthesis; or
- Subject has a pre-existing pulmonary arterial (PA) hypertension (PA systolic pressure exceeds 40 mmHg or RV systolic pressure (RVSP) as estimated by echo exceeds 40 mmHg), or significant physiologically impairing lung disease; or
- Subject has a pre-existing pacing or defibrillation leads; or
- Subject has current implantation of either conventional or subcutaneous implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT); or
- Subject has an implanted vena cava filter; or
- Subject has evidence of thrombosis in one of the veins used for access during the procedure; or
- Subject has an implanted leadless cardiac pacemaker