St. Jude Medical
15900 Valley View Court
Sylmar, CA 91342 USA
Main 818 362 6822
Fax 818 364 5814

ST. JUDE MEDICAL

October 28, 2016

Study: Nanostim™ Leadless II IDE/CAP

Subject: Leadless II IDE/CAP Study Pause

Dear Leadless II Investigator,

St. Jude Medical (SJM) was made aware of seven (7) reports worldwide of lost telemetry and pacing output as a result of a battery malfunction associated with SJM Nanostim Leadless Cardiac Pacemaker (LCP) devices, Model Number **S1DLCP.** Due to these events, we have decided to pause Nanostim LCP implants in the Leadless II IDE/CAP study.

To date, among 1,423 devices implanted worldwide, seven (7) patients have presented with Nanostim LCPs that could not be interrogated, respond to magnet mode or provide pacing therapy. These seven (7) events occurred between 29 and 37 months post implant. One hundred eleven (111) patients have completed the 2.5 year post-implant follow-up.

Symptomatic bradycardia was identified in one (1) patient while six (6) patients were asymptomatic and had their device malfunction detected during a routine scheduled follow-up visit. No patient injuries have been reported in association with the loss of bradycardia pacing therapy.

In all four (4) cases attempted, physicians successfully retrieved the devices, three (3) of those devices have been returned to SJM for analysis with the fourth pending return. In these four (4) cases, two (2) patients received another LCP, one (1) patient received a traditional pacemaker system and one (1) patient has not yet undergone device replacement. In two (2) of the remaining three cases, the physician did not attempt to retrieve the device and implanted a traditional pacemaker system after abandoning the LCP. In the remaining and most recent case, the patient has not yet had their system removed or replaced.

Mode and Identification of Battery Malfunction

Analysis of the returned units has found decreased battery capacity due to reduced electrolyte, resulting in high internal battery resistance. This disrupts the required capacity for proper device function and reduces device longevity.

Referring to a previously measured battery voltage may not provide an indication of continued normal operation as battery voltage remains normal under these circumstances. The Recommended Replacement Time (RRT) indicator will not be triggered as the battery voltage will remain above RRT in these devices. Battery malfunction may be indicated with a loss of telemetry/communication with the implanted device and/or loss of pacing and magnet mode operation.

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Estimation of Rate of Battery Malfunction

To date, seven (7) reported devices (0.50%) of 1,423 implanted devices worldwide have exhibited battery malfunction at 29 to 37 months after implant and 1,397 affected devices remain in service worldwide and, therefore, are potentially at risk.

Patient Management Recommendations

In consultation with our Leadless II IDE and our Leadless Postmarket Study Steering Committees we recommend the following:

- **Do not implant unused devices and return them to St. Jude Medical**
- **Do not rely on the RRT indicator to identify a battery that may potentially malfunction. However, if the RRT indicator does trigger, replace the device per standard practice**
- **Do not perform AV Node ablation in patients with an existing Nanostim LCP without another functional pacing system implanted**
- **For patients who have not previously been documented to be pacemaker dependent, re-assess patients in-office for pacemaker dependence**
- **For non-pacemaker dependent patients with devices of implant duration ≥ 24 months, more intensive follow-up and monitoring is recommended**
    - Implant Duration **≥ 24 months**: Request follow-up as soon as possible to assess the status of the battery. Then, monthly follow-up is recommended through in-office visits or a reliable method of tele-monitoring of heart rate and electrocardiogram
    - Implant Duration **< 24 months**: Continue follow up per protocol
- **For pacemaker dependent patients, device replacement is recommended (priority should be for patients with implants of longer duration)**
    - Identify and treat patients as quickly as possible
    - Interrogate the device and identify the ability to communicate with the device and the patient's underlying rhythm
    - Determine the strategy for management, including a decision whether to retrieve or abandon the Nanostim LCP, based on the individual patient's clinical history and overall medical condition. Use a temporary pacemaker for backup pacing while replacing the Nanostim device where clinically indicated
    - If the device is to be retrieved, use the Nanostim retrieval system as per the standard procedure described in the instructions for use
    - If the device will not be retrieved or if retrieval was attempted and not possible, implant a new pacemaker lead (bipolar) at a distance from the existing LCP to prevent long-term mechanical and electrical interactions. Confirm the location using multiple radiographic views

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- After implantation of the new pacing system, if it is possible to communicate with the LCP, turn "OFF" the abandoned LCP system. If the LCP device cannot be turned "OFF", consider programming the newly implanted system a minimum of 5 bpm faster than the LCP in order to inhibit the Nanostim device

A patient letter is included for you to provide your patients with information regarding this advisory.

Please return any explanted devices to SJM for further evaluation. We will provide follow-up information as future enhancements and methods are developed to assist in the management of devices that are at risk for this battery malfunction.

Should you have questions about patient management, please contact St. Jude Medical Technical Services at 1-800-722-3774 which is available 24 hours a day, 7 days a week.

We apologize for any difficulties this may cause you and your patients.

As a truly innovative device, we continue to learn from our investigators and will build upon the first generation Nanostim to create a platform technology that will transform the treatment of cardiac arrhythmias. Our product development team is working to implement new safeguards that detect causes of reduced longevity in an effort to protect patients whose devices may be nearing the end of their battery life. Additionally, we are working on an enhanced battery design to ensure the longevity of the next-generation of Nanostim leadless pacemakers.

We thank you for your continued participation in the Leadless II IDE/CAP study. Please continue to follow the patients per patient management recommendations and forward a copy of this letter to your IRB. If you have any questions about the Leadless II IDE/CAP study, please contact your local field clinical team or study manager, Melanie Turkel +1 408 522 6108; E-mail: mturkel@sjm.com).

Sincerely,

Mark Carlson
Vice President, Global Clinical Affairs