



November 17, 2017

Study: Nanostim™ Leadless II IDE/CAP

Subject: Leadless II IDE/CAP Study Pause

Dear Leadless II Investigator,

As part of Abbott's post market surveillance and clinical trial monitoring processes, we have been made aware of docking button detachments that have occurred following implant or during attempted retrieval of Nanostim™ Leadless Cardiac Pacemaker (LCP) devices, Model Number **S1DLCP**. The docking button is a small component (3.6 mm diameter) and is connected to the end of the LCP by two cables. This component is necessary for docking the LCP to the retrieval catheter during a retrieval procedure.

To date, among 1,423 devices implanted worldwide, three instances of a detached docking button have been reported. One case occurred during a retrieval attempt; there have been 93 retrieval attempts. Two cases, identified on chest x-ray, occurred several months after implant in LCPs that were not subject to attempted retrieval. In these cases, the device was either deactivated and a new system implanted, or the device continued to be used.

There have been no serious injuries reported. In the instance associated with LCP retrieval, the detached docking button migrated to a sub branch of the pulmonary artery and in the other two cases, the detached docking button remained embedded in the right ventricle. In all three cases that have occurred, there has been no impact to the electrical function (e.g., pacing, sensing, communication) and no clinical impact or symptoms resulting from the docking button detachment or exposed cables.

Worldwide implants of the Nanostim™ device remain halted as Abbott continues to investigate the issue. During this time, we wanted to make you aware as you consider the management of your patients.

Patient Management Recommendations

The following patient management recommendations have been developed in consultation with our Leadless Steering Committee members after discussions detailing the occurrences and the potential clinical impact associated with detached docking buttons:

- Continue following patients as per recommendations of the October 2016 Battery Malfunction for Nanostim™ LCP advisory (refer to Appendix).
- Retrieval of an implanted Nanostim™ LCP with an intact docking button confirmed radiographically remains an option, but should only be considered if the procedure can be performed as per the specifications contained in the instructions for use.

- If a detached docking button has been identified, Nanostim™ LCP retrieval is not recommended. In the rare situation where retrieval is the only management option, please contact the Abbott Clinical Study Team for further guidance.
- Prophylactic imaging for the sole purpose of determining if the docking button is intact is not recommended due to the effects of radiation and lack of any clear clinical actions based on results of imaging alone. If the option of Nanostim™ LCP retrieval is being considered, final imaging decisions should take into account the individual patient circumstances and preferences.
- If a detached docking button is identified, continue to follow the patient as per the Clinical Study Protocol and report the incident to Abbott.

A patient letter is included in this packet for you to provide your patients with information regarding this advisory. Please obtain IRB approval before providing to your patients.

Should you have questions about patient management, please contact your Abbott Clinical Study Team or Abbott Technical Services at +1-800-722-3774 which is available 24 hours a day, 7 days a week.

Please continue to follow the patients per study protocol 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 (Tel: +1-408-522-6108; E-mail: mturkel@sjm.com).

Sincerely,



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APPENDIX

October 2016 Battery Malfunction Patient Management Recommendations

- **Do not implant unused devices and return them to Abbott (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 \geq 24 months, more intensive follow-up and monitoring is recommended**
 - **Implant Duration \geq 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
 - 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