# FIELD SAFETY NOTICE UPDATE
## Docking Button Detachment in Nanostim™ Leadless Cardiac Pacemaker

05 April 2018

Dear Doctor,

This communication provides an update regarding the investigation of the Nanostim Leadless Cardiac Pacemaker (LCP) detached docking button for which the initial Field Safety Notice (FSN) was issued in November 2017.

There is no change to the existing November 2017 FSN patient management recommendations as a result of the investigation. These are listed in the appendix.

Incidence of Docking Button Detachment

Abbott would like to inform you of one additional detachment that was identified on fluoroscopy prior to a retrieval attempt several years after LCP implant. The docking button appeared to be embedded in the RV. No injuries have been reported to date as a result of this detachment.

To date, among 1,423 devices implanted worldwide, four instances of a detached docking button have been reported. This equates to a docking button detachment rate of 0.28% and a rate during retrieval of 0.85% for Nanostim LCP's.

In all cases there has been no impact to the electrical function (e.g., pacing, sensing, and communication) and no patient harm, clinical impact, or symptoms resulting from the docking button detachment or exposed docking button retention cables.

Root Cause Investigation

Our investigation has concluded that the most likely root cause is fatigue, ultimately causing fracture of the cables that connect the docking button to the Nanostim Leadless Pacemaker. Bench testing showed that docking button deflection results in micro-cracking of the cables that leads to fatigue, with the extent of fatigue affected by the magnitude and orientation of deflection. Anatomical factors, such as tissue growth encapsulating the docking button, may increase docking button deflection with cardiac motion. As there have only been four reported events (3 under in-vivo conditions and 1 during a retrieval), the impact of implant related factors on this mechanism is not definitive.

Failure Rate Projection

Failure rate projections have been made based upon review of 281 Nanostim patients subject to either system revisions, retrieval attempts, or x-rays. The most likely projected failure rate increases gradually at approximately 1% every 3 years.

Although fatigue is generally thought to be time dependent, the rate of docking button detachment may not be directly correlated with implant duration due to contributions of multiple factors which are patient specific and may not be identifiable. In the event of a detached docking button, the potential safety impacts may include:

- Embolization of Docking Button
- Intravascular Foreign Body where the docking button is retained in the heart
- Additional surgical intervention
- Perforation or bleeding

Please note that worldwide implants of the Nanostim™ device remain halted and the CE-mark has been temporarily suspended. Should you have questions about patient management, please contact your Abbott Clinical Study Team or Abbott Technical Services at +46-8474-4147 (EU), which is available 24 hours a day, 7 days a week. Further information on this Field Safety Notice can be found on www.sjm.com/notices.

Please continue to follow the patients per the study protocol and work with your local field clinical representative to forward a copy of this letter to your ethics committee, as applicable. If you have any questions about the Leadless Observational Study, please contact your local field clinical team or the study manager, Pascale Ducloux (Tel: +32 2 774 67 09; E-mail: pducloux@sjm.com).

Sincerely,

Robert Blunt

Robert Blunt
Divisional Vice President, Quality
Cardiac Rhythm Management

# APPENDIX

November 2017 Detached Docking Button 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 (see below).
- 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 removal is the only management option, Abbott recommends the procedure be performed by physicians experienced in foreign body removal, including using the femoral approach. 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 and relevant Competent Authority, as appropriate.

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 ≥ 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
    - 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