SJM Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium
Main +32 2 774 68 11
Fax +32 2 772 83 84

# Important Medical Device Information

February 20, 2015

Subject: Nanostim™ Leadless Pacemaker & Delivery System Catheter, Model S1DLCP

Dear Doctor,

The purpose of this communication is to inform you of the current status of the Nanostim™ Leadless Pacemaker System Post Market Clinical Follow up (PMCF) study. St. Jude Medical is analyzing interim data from our worldwide Nanostim™ studies with a focus on adverse events. These data will be shared for review with regulatory agencies, including the Notified Body, Competent Authorities (European national regulatory bodies) and, where appropriate, research ethics committees.

In consultation with the UK Medicines and Healthcare products Regulatory Agency (MHRA), which is coordinating on behalf of other Competent Authorities, we are temporarily suspending new implants in the PMCF study at participating centers during this review. This temporary suspension in enrollment is not due to a new safety concern. It is a precautionary measure to allow for a thorough comparison of the risks and benefits of the Nanostim™ treatment option, following further incidents of pericardial effusion since the PMCF study resumed in June 2014 including in the IDE study. See table 1 below for details.

Table 1: Detailed summary of Serious Adverse Device Effects (SADEs) as of January 5, 2015

| **Serious Adverse Device Effects** | **Nanostim™ EU Post Market – Pre Pause (December 23, 2013 - April 17, 2014) N = 147 pts** | **Nanostim™ EU Post Market- Post-Pause (June 2, 2014 – January 5, 2015) N = 93 pts** | **Nanostim™ IDE (February 4, 2014 – January 5, 2015) N = 322 pts** | **Nanostim™ EU Post Market (Post Pause) + IDE N = 415 pts** |
|---|---|---|---|---|
| Pericardial Effusion or Perforation (total) | 4.1% (6) | 2.2% (2) | 1.6% (5) | 1.7% (7) |
| - Observations[3] | 0% (0) | 1.1% (1) | 0.3% (1) | 0.5% (2) |
| - Complications[4] | 4.1% (6) | 1.1% (1) | 1.2% (4) | 1.2% (5) |
| Dislodgment | 1.4% (2) | 0.0% (0) | 1.9% (6) | 1.4% (6) |
| Intermittent Capture or Failure to Capture or Elevated Threshold | 0.0% (0) | 1.1% (1) | 1.2% (4) | 1.2% (5) |
| Inadvertent device release during implant resulting in retrieval and conventional pacemaker implant | 0.7% (1) | 0.0% (0) | 0.0% (0) | 0.0% (0) |
| Access Site Bleeding Event or Hematoma | 0.7% (1) | 0.0% (0) | 1.2% (4)[1] | 1.0% (4) |
| Pulmonary Embolus | 0.0% (0) | 0.0% (0) | 0.3% (1)[2] | 0.2% (1) |
| Infection | 0.0% (0) | 0.0% (0) | 0.0% (0) | 0.0% (0) |

[1] Two of these events were observations.
[2] This event was an observation.
[3] Observations are defined as SADEs that do not require invasive interventions.
[4] Complications are defined as SADEs that require invasive interventions (also includes abandonment of the procedure and implantation of a conventional pacemaker).

Please do not implant the Nanostim™ device and place any Nanostim™ devices in your possession into quarantine. Your St. Jude Medical representative will retrieve those devices shortly. There is no change to existing patient follow-up requirements.

Upon completion of the review we will determine the most appropriate conditions and timeframe for resumption of implants at the PMCF study centers. No further enrollment will take place until we receive approval from the above agencies.

Please review this information with all members of your staff who need to be aware of the contents of this communication.

St. Jude Medical is committed to providing the highest quality products and support. If you need any further information or support concerning this issue, please contact your local St. Jude Medical Representative or Technical Support at +46 8 474 4147.

Sincerely

[redacted]

Roland Gerard
VP, Quality International Division
and Regulatory Affairs EMEA
St. Jude Medical