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May 11, 2017

Study: Nanostim™ Leadless Observational Study
CIP #: LCP005

Sponsor:
St. Jude Medical (now Abbott)
Clinical Studies Organization
15900 Valley View Court
Sylmar, CA 91342.
USA

Subject: Nanostim™ Leadless Pacemaker - Leadless Observational Study re-start

Dear Dr/Pr XXX,

On October 28 2016, St. Jude Medical (SJM) issued a field safety notice to all participating centers confirming that new implants in the Leadless Observational Study were paused after seven (7) reports worldwide of lost of telemetry and pacing output as a result of a battery malfunction with SJM Nanostim Leadless Pacemaker devices, model number S1DLCP.

As previously communicated, our product development teams had been working on an alternate battery design of the next generation of Nanostim Leadless Pacemaker which was submitted to the Notified Body for review. The Notified Body has now approved our next generation of Nanostim Leadless Pacemaker, model number LSP102 with a new battery. With this approval, we will be able to restart Nanostim implants within the Leadless Observational Study at selected sites upon approval of the amended protocol by local Ethics Committees, and where appropriate, by Competent Authorities.

Your local clinical Abbott representative will contact you for the submission of this updated protocol to your local Ethics Committees.

Should you have any questions, you can contact me by phone (+32 27 74 67 09) or email (pducloux@sjm.com) or your local clinical representative.

Sincerely,

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.Abbott