



**URGENT: MEDICAL DEVICE RECALL NOTICE**  
**For 8-Channel Lead for the St. Jude Medical Infinity™ DBS (Deep Brain Stimulation) System**

UDI: 05415067020635, 05415067030306, 05415067020680, 05415067030320

October 11, 2018

Dear Hospital Administrator,

Abbott is committed to ensuring our customers receive the most current information available to provide optimal care for patients. To that end, our records indicate that your institution received Abbott/St. Jude Medical 8-Channel Lead for the St. Jude Medical Infinity™ DBS System that may be impacted by an isolated manufacturing issue. Please refer to Appendix A for the list of units. While we continue to investigate this issue, these leads should not be implanted and will need to be returned.

As background, we believe that some of the listed leads may contain an electrode that does not conform to our material specification. In total, there have been four (4) reports from (2) centers describing that the most proximal stimulation tip electrode (electrode position 4) appeared lighter than the more distal electrodes when radiographed. There have been no reports of patient harm to date. Further communication with additional details about this action, inclusive of management recommendations for any patients that may have been implanted with an affected lead, will be forthcoming as soon as possible.

Your Abbott representative will assist you in removing these leads from your account and will facilitate replacing them. We are requesting your support on the removal and return of these leads. The FDA has been notified of this activity.

In the meantime, if you or your physicians have any questions, please contact your local Sales Representative or Abbott Support at 1-800-727-7846 (Opt3).

We sincerely apologize for any difficulties or inconvenience that this may cause. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for assisting us with this process.

Sincerely,

A handwritten signature in black ink that reads 'Christopher J. Gallivan'.

Christopher J. Gallivan  
Divisional Vice President, Quality  
Abbott Neuromodulation