



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 10, 2018

Hospital
Address
City, State Zip

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 Competent Authorities of the countries impacted by this FSCA have been notified of this activity.

In the meantime, if you or your physicians have any questions, please contact your local Osman, Mohamed <mohamed.osman@abbott.com> 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,

Christopher J. Gallivan
Divisional Vice President, Quality
Abbott Neuromodulation

APPENDIX A: Affected Leads

Model no.	Serial No.	Batch	Material Description	Ship to Name
6172ANS	17086337	6197963	8CH SJM INF Lead Kit, 40cm, 0.5, Black	AL-JEEL MED.& TRAD CO LTD
6172ANS	17086342	6197963	8CH SJM INF Lead Kit, 40cm, 0.5, Black	AL-JEEL MED.& TRAD CO LTD
6172ANS	17086355	6197963	8CH SJM INF Lead Kit, 40cm, 0.5, Black	AL-JEEL MED.& TRAD CO LTD
6172ANS	17086357	6197963	8CH SJM INF Lead Kit, 40cm, 0.5, Black	AL-JEEL MED.& TRAD CO LTD
6170ANS	17145439	6244627	8CH SJM INF Lead Kit, 30cm, 0.5, Black	AL-JEEL MED.& TRAD CO LTD
6170ANS	17145459	6244627	8CH SJM INF Lead Kit, 30cm, 0.5, Black	AL-JEEL MED.& TRAD CO LTD
6170ANS	17145461	6244627	8CH SJM INF Lead Kit, 30cm, 0.5, Black	AL-JEEL MED.& TRAD CO LTD
6170ANS	17145463	6244627	8CH SJM INF Lead Kit, 30cm, 0.5, Black	AL-JEEL MED.& TRAD CO LTD