



**URGENT MEDICAL DEVICE RECALL NOTICE**  
**For Radiofrequency Disposable Grounding Pad**  
**Model RF-DGP-L, Lots 810319004, 810319005 and 810319021**

UDI: 05415067028914

October 14, 2019

Dear Abbott Customer,

To help ensure patients are provided with optimal care, Abbott is voluntarily recalling Abbott Medical Radiofrequency Grounding Pad Model RF-DGP-L, lot numbers 810319004, 810319005 and 810319021, that were impacted by an isolated manufacturing issue. Our records indicate that your institution received product from one or more of these lots. Any remaining inventory from these lots should not be used and will need to be returned to Abbott. All other lots of model RF-DGP-L or the alternative model (RF-DGP-S) are not impacted and can be used. There are no other actions required on your part beyond completing the accompanying Acknowledgment Form and returning any remaining unused devices associated with this notice.

As background, some of the grounding pads within the affected lots were manufactured with the protective release liner in an incorrect orientation. When attempting to remove this disposable release liner, a clear film may be left on the grounding pad which may interfere with patient skin contact and lead to uneven heating. To date, there have been ten (10) reports from five (5) centers that have identified thirty (30) devices with the nonconforming release liner. There have been five (5) reports of burns related to the use of these affected devices when a clear film remained on the pad. The current observed incidence of the nonconformance across the three lots is 0.330%, and the observed incidence of burns is 0.055%.

**Next Steps**

Your Abbott representative will assist you in returning these devices and facilitate replacing the affected devices with conforming product. Please maintain a record of this notice along with a copy of the completed Acknowledgement Form to ensure effectiveness of this communication.

A copy of this letter is available on [www.neuromodulation.abbott/notices](http://www.neuromodulation.abbott/notices). Should you have questions about this issue, please contact your local Abbott Representative or Abbott Support at 1-888-655-3500 (Option 2) (U.S.), 8:30 a.m. - 5:30 p.m. Central Time Monday through Friday. For assistance with order replenishment, please call 1-888-655-3500 (Option 1).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. To submit your report:

- Complete the voluntary Form FDA 3500 online;
- Call 1-800-FDA-1088 to report by telephone; or
- Download the form from [FDA.gov](http://FDA.gov) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form or submit by fax to 1-800-FDA-0178 (Send only page 1 plus any continuation pages - do not send instruction pages.).

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