



**URGENT MEDICAL DEVICE RECALL NOTICE**  
**For Classic Radiofrequency Cannula - Curved**  
**Model C-1005-S, Lot 6865795**

GTIN: 05415067028693

November 11, 2019

Dear Abbott Customer,

To help ensure patients are provided with optimal care, Abbott is voluntarily recalling Abbott Medical Classic Radiofrequency Cannula – Curved, Model C-1005-S, lot number 6865795, which was impacted by an isolated manufacturing issue. Our records indicate that your institution received product from this lot. Any remaining inventory from this lot should not be used and will need to be returned to Abbott. All other lots of model C-1005-S or any of the other models of Classic Radiofrequency (RF) Cannula - Curved 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, a manufacturing error caused a single lot of 10 mm active tip length cannulas to be labeled as 5 mm active tip length cannulas. If an affected device is used, the risk of thermal injury is low because there are existing procedure mitigations, including imaging and motor testing, which confirm the intended placement prior to application of thermal RF energy. To date, there has been one (1) reported event where nonconforming devices were identified prior to use and there was no patient impact. The observed incidence rate of patient harm is 0.0%.

**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 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, appearing to read 'Christopher J. Gallivan'.

Christopher J. Gallivan  
Divisional Vice President, Quality  
Abbott Neuromodulation