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Urgent Field Safety Notice
Pulmonary Vein Ablation Catheter® GOLD (PVAC GOLD)
Instructions for Use Update

March 2019

Medtronic reference: FA859

Dear Healthcare Professional,

This notification is to provide you with important information regarding an update to the Instructions for Use (IFU) for the Medtronic Pulmonary Vein Ablation Catheter (PVAC GOLD), Model 990078. This IFU revision adds the current recommendations for reducing the potential for phrenic nerve injury. This letter contains the language of the IFU update. There are no other model numbers of Medtronic devices affected by this revision.

Issue Description

Phrenic nerve injury is a known possible complication for atrial fibrillation ablation.[1,2] Phrenic nerve injury is caused by thermal damage to the phrenic nerve. This complication has not been associated with product malfunctions or failures. The observed rate of occurrence for this issue, from August 2015 through October 2018, is 0.073% and there have been zero (0) vigilance reports filed as a result of this issue.

IFU Update Language

> **To reduce the potential for phrenic nerve injury, assess for proximity of the ablation catheter to the nerve using an appropriate technique such as pacing for local phrenic capture, prior to ablation. Stop ablation immediately if phrenic nerve impairment is observed and assess for injury.**
>
> **NOTE:** When released in your geography, the updated IFU language may differ slightly from the content of this communication based on the IFU approved by local regulatory agencies, where required.

Medtronic is not retrieving product from the field. Patients who have been, or will be, treated with PVAC GOLD should continue to be managed according to your standard patient management protocols.

Customer Actions

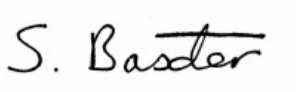
Please complete the following actions:

- Review the **IFU Update Language** regarding potential for phrenic nerve injury as provided in this letter.
- Please share this information with healthcare professionals in your facility that use PVAC GOLD. Also share this information with any other organization where these devices may have been transferred.

Please maintain a copy of this notice in your records. Medtronic has notified the Competent Authority of your country of this action. We remain committed to continuous improvement of our products and services to enable you to manage your patients in a safe and effective manner.

If you have any questions, please contact your Medtronic Representative at 01923 212213.

Sincerely,



Samantha Baxter
Regulatory Affairs Manager, UK and Ireland

[1] Calkins H, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE Expert consensus statement on catheter and surgical ablation of atrial fibrillation. Heart Rhythm. 2017;14(10):e275-e444.
[2] Kirchhof P, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. European Heart Journal. 2016;37:2893-2962.