Medtronic, Inc.
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Urgent Field Safety Notice
IN.PACT® Amphirion Drug-Eluting Balloon (DEB)

November, 2013 Medtronic reference # FA597

Dear Healthcare Professional (Hospital Administrator, OR Manager, and Risk Manager),

Based on data from the IN.PACT® DEEP clinical study, Medtronic has decided to voluntarily recall and stop selling the IN.PACT Amphirion drug-eluting balloon (DEB). Only the IN.PACT Amphirion DEB is subject to this recall. Other products in the IN.PACT DEB product family are not subject to this recall.

IN.PACT DEEP is a post-market, multicenter, randomized controlled trial of below-the-knee revascularization in patients with critical limb ischemia (CLI). The IN.PACT Amphirion DEB did not meet its safety and efficacy endpoints relative to the percutaneous transluminal angioplasty (PTA) control. The study also identified a potential safety signal given a trend towards an increased rate of major amputations in the DEB study arm.

Causality between major amputation and use of the IN.PACT Amphirion DEB could not be established or excluded. Subset and multivariate analyses of the data have not revealed any specific cause, and no other evidence from the trial has explained this finding. The IN.PACT DEEP 12 month results will be presented at a scientific session during the upcoming Leipzig Interventional Course (LINC) in Leipzig, Germany to be held January 28-31 2014.

Other Medtronic IN.PACT DEB products (IN.PACT Admiral, IN.PACT Pacific and IN.PACT Falcon) were not involved in the IN.PACT DEEP study and are not subject to this recall. The safety and efficacy of this medical technology in the femoro-popliteal and coronary vascular beds have been demonstrated in randomized clinical trials.

Our records show that your facility has received units of the IN.PACT Amphirion DEB. As a result, Medtronic requests that you immediately take the following actions:

1. Remove and quarantine all units of the IN.PACT Amphirion DEB that remain in your inventory.
2. Return all unused IN.PACT Amphirion DEB units to Medtronic. Your local Medtronic representative will assist you with this device return. If the product is hospital owned your Medtronic representative can assist you with receiving financial credit.

For units of the IN.PACT Amphirion DEB that have been used, no additional action is necessary outside of your patient management protocols already in process for CLI patients.

Medtronic has taken the necessary steps to prevent any future shipment of the IN.PACT Amphirion DEB. Regulatory agencies are being notified about this recall as applicable.

Medtronic

Please share this notification with others in your organization as appropriate. If IN.PACT Amphirion DEB units have been forwarded to another facility, please notify that facility accordingly and facilitate the retrieval of all unused units.

We apologize for the inconvenience this may cause you; please be assured that patient safety and product quality remain our primary concern. Should you have any questions, please contact your Medtronic representative or Medtronic Customer Service.

Sincerely,