



## URGENT FIELD SAFETY NOTICE/ DEVICE RECALL

COMMERCIAL NAME: HT Connect Peripheral Guide Wires  
FSCA-Identifier: November 25, 2013  
Type of Action: Product Recall

### Attention: Dear Abbott Vascular Distributor

Abbott Vascular has initiated a voluntary field action for HT Connect Peripheral Guide Wires due to a small number of devices exhibiting partial delamination of the PTFE coating. To date, the frequency of worldwide reported incidents of delamination of the coating is 0.08%. While there have been no long term or irreversible patient effects reported, potential risks associated with delamination of the coating include embolism, thrombus and occlusion in the peripheral vessels.

This action does not affect patients having successfully undergone endovascular PTA procedures.

#### What you should do:

Our records indicate that HT Connect Peripheral Guide Wires have been shipped to your account. The use of these devices should cease immediately. Please review your inventory for the following part numbers and identify all customers who have received affected units. Notify all impacted customers and retrieve the unused units. Return all unused devices to Abbott Vascular.

Part Number	Description
1012587	018 HT CONNECT 145 CM
1012588	018 HT CONNECT 195 CM
1012589	018 HT CONNECT 300 CM
1012590	018 HT CONNECT FLEX 145 CM
1012591	018 HT CONNECT FLEX 195 CM
1012592	018 HT CONNECT FLEX 300 CM
1012593	018 HT CONNECT 250T 145 CM
1012594	018 HT CONNECT 250T 195 CM
1012595	018 HT CONNECT 250T 300 CM

#### What Abbott Vascular is doing:

Abbott Vascular has ceased distribution of the product while evaluating appropriate corrective and preventive actions. Abbott Vascular will work with you to replace returned units with similar product, pending availability. The appropriate regulatory agencies have been notified of this action.

We regret any inconvenience this may cause you. Abbott Vascular is committed to providing high quality products and ensuring customer satisfaction.

Sincerely,

Hassan Hamouda  
General Manager Abbott Vascular  
Middle East, North Africa and Turkey