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Abbott Vascular
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# URGENT FIELD SAFETY NOTICE / PRODUCT RECALL

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

**Attention: Implanting Physician**

Dear Valued Abbott Vascular Customer:

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 work with your local Abbott Vascular account representative to review your inventory for the following part numbers, complete the attached Field Action Reconciliation / Effectiveness Check Form and return it with 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 | 18 HT CONNECT FLEX 145 CM |
| 1012591 | 18 HT CONNECT FLEX 195 CM |
| 1012592 | 18 HT CONNECT FLEX 300 CM |
| 1012593 | 18 HT CONNECT 250T 145 CM |
| 1012594 | 18 HT CONNECT 250T 195 CM |
| 1012595 | 18 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.



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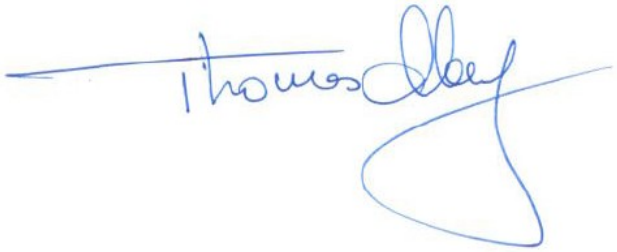
We regret any inconvenience this may cause you. Abbott Vascular is committed to providing high quality products and ensuring customer satisfaction.

Sincerely,



Thomas Monby
Business Unit Manager, Endovascular & VC, UK, Ireland & Nordics

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## Effectiveness Check Form

Customer Account #_____
Account Name _____
Address _____
_____
Phone _____
(Information required for regulatory effectiveness check)

I confirm that I have received, read and understood the Field Safety Notice/Product Recall communication.

Check One:

☐ **No devices will be returned.** A thorough search for all affected HT Connect Guide Wires has been completed and none remain in inventory.

☐ **Devices will be returned.** A thorough search has identified affected HT Connect Guide Wires that will be returned.

**RGA Number:** _____

_____ _____ _____
***Customer Name/ Title (print)*** ***Signature*** ***Date***

**This form is to be returned to Abbott Vascular**

- Return this signed form to your Abbott Vascular Representative, or
- Fax this signed form to +46 8 546 568 00



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