URGENT FIELD SAFETY NOTICE/ DEVICE RECALL
Hi-Torque Command™ 18 ST Guide Wire

Commercial Name: Hi-Torque Command™ 18 ST Guide Wire
FSCA-Identifier: HT Command 18 ST FSCA, December 23, 2021
Manufacturer: Abbott Vascular Santa Clara, SRN# US-MF-000003850
Type of Action: Device Recall

Attention: Risk Manager or Healthcare Professional

Dear Valued Abbott Customer:

Abbott has initiated a field action for 3 lots of the Hi-Torque Command™ 18 ST Guide Wire, a peripheral guide wire intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal angioplasty (PTA). 415 devices were distributed only in European countries.

Product	Part Number	GTIN/UDI	Lot Number	Expiration Date
HT Command 18 ST 210cm	1013784	08717648212390	1102561	9/30/2023
			1102562	9/30/2023
HT Command 18 ST 300cm	1013785	08717648212406	1101861	9/30/2023

Devices from these lots may have a manufacturing defect, discovered internally, that can result in peeling of the distal polymer coating. Testing indicates the peeling can result in separation of the distal polymer coating under normal use (0.26% rate). While there have been no customer reports of performance issues or patient adverse events, potential risks associated with use may include polymer material remaining in the vasculature, thrombus, and embolism.

This action does not affect patients having successfully undergone procedures using these devices.

What action should you to take?

- Immediately stop using devices from these lots
- Review your inventory and complete the provided Effectiveness Check Form
- Return the form and return all unused devices to Abbott
- Share this notification with relevant personnel in your organization
- Report any occurrence of product performance issues or patient adverse events to Abbott

What action is Abbott taking?

- Abbott has taken immediate action to stop shipping devices from affected lots and to mitigate recurrence of the issue in production.
- The investigation has determined there are no other affected products or lots in distribution.
- The investigation is in process to establish appropriate corrective actions.
- Abbott will work with you to replace inventory.
- The appropriate regulatory agencies have been notified of this action.

We regret any inconvenience this may cause you and appreciate your patience. Abbott is committed to providing high quality, compliant products and ensuring customer satisfaction. If you have any questions, please do not hesitate to contact your local Abbott Representative or Customer Service department on x-xxx-xxx (Mo.-Fr. from 08 am to 05 pm).

Sincerely,

Abbott Medical GmbH- Betriebsstätte Wetzlar

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Effectiveness Check Form

Customer Account # _____

Account Name _____

Address _____

_____

(Information required for regulatory effectiveness check)

After reviewing your inventory for these affected devices, complete this form and return this form and any affected devices to Abbott per the instructions below.

Product	Part Number	GTIN/UDI	Lot Number	Expiration Date
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Check One:

☐ A thorough search for all affected devices has been completed and no affected units remain in inventory. **No devices will be returned.**

☐ Affected devices have been identified and are being returned

RGA Number: _____

_____ _____ _____

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

This form is to be returned to Abbott

- If returning product, call Customer Service <x-xxx-xxx> to receive RGA number.
- Record RGA number above.
- Scan and email this form to <x-xxx-xxx> *or* fax to <x-xxx-xxx>
- Return a copy of this completed form with the returned product.