



URGENT MEDICAL DEVICE RECALL NOTICE
Fast-Cath™ Hemostasis Introducer
Model 406143, Lots 6917183, 6950628, 7099144
GTIN: 15414734014219

December 9, 2019

Dear Abbott Customer,

Abbott is voluntarily recalling three lots of Abbott Fast-Cath™ Hemostasis Introducer (Model 406143, lot numbers 6917183, 6950628, and 7099144). Our records indicate that your institution received product from an affected lot. All other lots of model 406143 and any of the other models of Fast-Cath™ Hemostasis Introducer are not impacted and can be used.

As a result of a manufacturing error, these three lots of Fast-Cath™ Hemostasis Introducer devices contained 8F sized dilators and sheaths instead of the expected 8.5F devices. If an affected device is used during a procedure, resistance may be encountered while inserting the catheter. If resistance is encountered, the device would require replacement prior to proceeding. The risk of patient harm is low and is limited to risks associated with a delay in procedure. To date, there have been three (3) customer reports of nonconforming devices, none of which were associated with patient impact.

Next Steps:

Your Abbott representative can assist you in returning these devices.

- Any remaining inventory from the affected lots should not be used.
- Complete and return the accompanying Acknowledgment Form to Abbott.
- Return any remaining unused affected devices to Abbott.

Please pass this notice to all those who need to be aware of it within your organization and maintain a record of this notice along with a copy of the completed Acknowledgment Form to ensure effectiveness of this communication.

Should you have questions about this issue or for order replenishment, please contact your local Abbott Representative.

The appropriate Regulatory Agencies have been notified of this action.

We sincerely apologize for any difficulties or inconvenience that this may cause. Please know that Abbott is committed to providing the highest quality products and support, and we thank you for assisting us with this process.

Sincerely, 

Steven Eldridge
Divisional Vice President Global Quality and Compliance
Abbott Vascular