Abbott

URGENT MEDICAL DEVICE RECALL NOTICE
Fast-Cath™ Trio Hemostasis Introducer
Model 406303, Lot 7133555

GTIN: 15414734203903

December 9, 2019

Dear Abbott Customer,

Abbott is voluntarily recalling one lot of the Abbott Fast-Cath™ Trio Hemostasis Introducer (Model 406303, lot number 7133555). Our records indicate that your institution received product from the affected lot. All other lots of model 406303 and any of the other models of Fast-Cath™ Trio Hemostasis Introducer are not impacted and can be used.

As a result of a manufacturing error, this one lot of Fast-Cath™ Trio Hemostasis Introducer devices contained 12F sized dilators and sheaths instead of the expected 14F devices. If an affected device is used during a procedure, resistance may be encountered while inserting the selected 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 seven (7) 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 this affected lot 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 Acknowledgement Form to ensure effectiveness of this communication.

Should you have questions about this issue or for order replenishment, please contact your local Abbott Representative or Abbott Support at 1-855-478-5833 (Option 1) (U.S.), 7:00 a.m. - 7:00 p.m. Central Time, Monday through Friday.

The appropriate Regulatory Agencies have been notified of this action. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. To submit your report:

- Complete the voluntary Form FDA 3500 online;
- Call 1-800-FDA-1088 to report by telephone; or
- Download the form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form or submit by fax to 1-800-FDA-0178 (Send only page 1 plus any continuation pages - do not send instruction pages).

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,

[redacted]

Melissa A. Owsley
Divisional Vice President, Quality
Abbott Electrophysiology