URGENT FIELD SAFETY NOTICE

EP-FA-2025-002

TactiFlex SE UniD Curve D, Model A-TFSE-D
TactiFlex SE UniD Curve F, Model A-TFSE-F
TactiFlex SE BiD Curve F-J, Model A-TFSE-FJ
TactiFlex SE BiD Curve D-F, Model A-TFSE-DF
TactiFlex SE BiD Curve D-D, Model A-TFSE-DD

12 September 2025

Dear Customer,

Summary

Abbott is issuing this advisory notice related to the TactiFlex™ Ablation Catheter, Sensor Enabled™. As part of our post-market surveillance and monitoring processes, Abbott has become aware of a limited number of tip detachment events during catheter removal from the packaging. Although the packaging has not changed since the introduction of the device (2022), improper removal from the packaging can result in tip damage. While most damaged tips (26 out of 29 instances) were detected prior to catheter insertion into patients, Abbott has experienced 3 recent instances where tips have detached and remained in the patient (incidence rate of <1:100,000). In all three (3) cases there were no further adverse outcomes reported to the patients. Abbott has made changes to the packaging tray design to help mitigate tip damage during catheter removal and has recently started to deploy the new packaging.

Description

The TactiFlex™ Ablation Catheter, Sensor Enabled™ family of catheters are packaged in a long, straight tray with a tip protector to prevent damage to the sensors in the catheter tip. Improper removal of the catheter from the tip protector can potentially break, or damage, the tip. In order to avoid damage to the tip, prior to lifting the distal tip out of the tray, one must ensure the distal tip has been fully retracted from the tip protector. The current IFU requires inspection of the packaging and catheter for damage and/or kinking prior to use.

Impact and Associated Risk

Tip detachment is most often detectable prior to use, and, if a tip detaches prior to insertion into the patient, the physician should replace the catheter. In the event the tip detaches during the procedure, there is the potential for embolism or migration of the detached material. This can potentially lead to respiratory compromise, hemodynamic instability, stroke, or ischemia. In all three (3) cases where users reported tip detachment during the procedure, none of these events have been reported.

Action Requested/Recommendations/Next Steps

- Continue following the product IFU by inspecting the packaging and catheter for damage and/or kinking prior to use.
- Review the guidance in Appendix A information on proper removal technique of the TactiFlex™ Ablation Catheter, Sensor Enabled™ from the packaging tray, ensuring to inspect the electrodes and catheter tip carefully for integrity and overall condition prior to use.
- Abbott has made changes to the packaging tray design to help mitigate tip damage during catheter removal from the packaging. The deployment of the new packaging has begun.

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Please complete the provided Acknowledgement Form with the assistance of your Abbott representative. This form ensures you are aware of the advisory notice and have been given an opportunity to ask questions.

Contact for Additional Information/Reporting and Customer Assistance

Adverse reactions or quality problems experienced with the use of this product may be reported to your Abbott Representative.

Summary Information

Please forward this notice to anyone in your organization who may need to be notified and maintain this notice for your records to ensure effectiveness of this communication.

Abbott is committed to providing the highest quality products and support. We apologize for any inconvenience this action may cause you, and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

If you have any questions or concerns, please contact your Abbott Sales Representative.

Thank you for your continued support.



Melissa Owsley
Divisional Vice President- Quality
Abbott Electrophysiology Division

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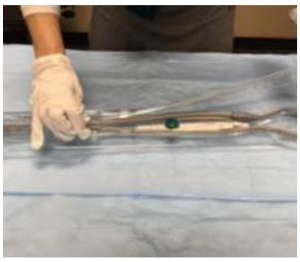
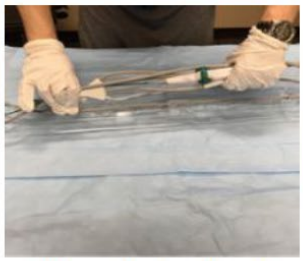
Appendix A. Proper Removal Technique



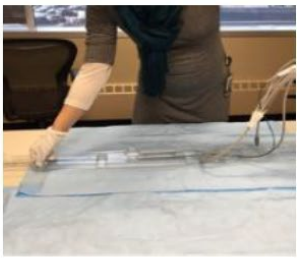
Pull up on plastic tabs and lift the outer plastic tray



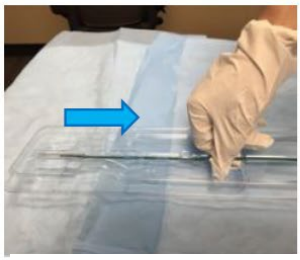
Pull up on plastic tabs and lift the inner handle plastic tray

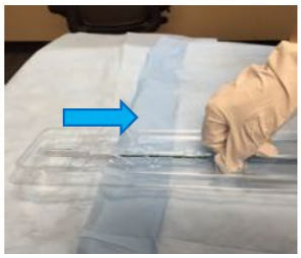


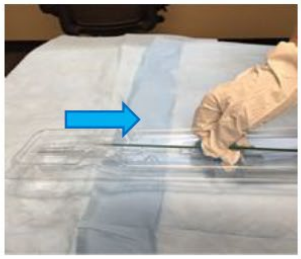
Pick up the handle and cabling together



Hold the handle & cabling and reach for the distal shaft



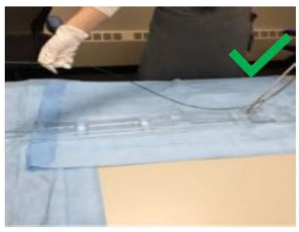




To retract the tip from the protective sleeve, pull back the catheter shaft in the axial direction and retract the tip fully from its protective sleeve prior to pulling up



It is important to instruct the EP staff that failure to retract the tip may result in damage



Pick up the handle and cabling together to remove