URGENT FIELD SAFETY NOTICE

TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™
Models: A-TCSE- DF, A-TCSE- DD

Abbott Medical
5050 Nathan Lane
Plymouth, MN 55442
USA

March 24, 2022

Dear Abbott Customer,

Abbott is voluntarily recalling 50 lots of the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ (models A-TCSE- DF and A-TCSE- DD). In certain instances, the TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ generates an error when initially connected to the TactiSys™ that states the "Contact Force Catheter is intended for single use only" and disables contact force sensing for affected catheters.

Our records indicate that your institution received product from one or more of the affected lots of models A-TCSE- DF and A-TCSE- DD attached as Appendix A to this letter. All other lots of TactiCath™ Contact Force Ablation Catheter, Sensor Enabled™ and any additional models are not impacted and can be used.

Scope of Problem
This issue is isolated to a specific manufacturing error for the lots listed in Appendix A, which results in an error message when the catheter is connected to the TactiSys™. This error message indicates that the catheter was previously date stamped with a first time use date – which incorrectly implies previous use of the device. These catheters have not been previously used in a procedure or reprocessed. This error will present during device preparation once the 19-pin connector is connected to the TactiSys™ equipment electrical socket as part of preparing the catheter prior to use. When this issue occurs, the catheter's contact force sensing feature is disabled.

Impact and Associated Risks
In the event this error message appears, the physician will need to either replace the device prior to use or continue the procedure without the use of the contact force sensing feature.

Based on our initial assessment, the primary risk associated with this error is a minimal delay of procedure to replace the device, with a low potential to result in physical harm. To date, there have been 398 customer complaints with no patient harm reported.

Next Steps
To help reduce risk, we are recommending:

- Do not use any remaining inventory from the affected lots listed in Appendix A.
- Return all remaining unused affected devices to Abbott. Your Abbott representative can assist you in returning these devices and obtaining replacements.

Please forward this notice to anyone within your organization who may need to be notified and maintain a record of this notice.

The appropriate Regulatory Agencies have been notified of this action.

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5050 Nathan Lane
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USA

Should you have questions about this issue, please contact your local Abbott Representative.

Abbott is committed to providing the highest quality products and support. Thank you for your assistance in this matter, and we sincerely apologize for any inconvenience this action may cause you.

Sincerely,

Divisional Vice President, Quality
Abbott EP Division

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Appendix A

Affected Lot Numbers			
8180723	8186860	8196343	8205760
8180900	8188124	8196367	8207547
8181043	8188351	8197913	8172360
8181068	8188844	8164687	8173365
8182131	8190306	8162700	8173840
8182658	8190438	8164730	8175413
8183581	8191524	8200249	8177349
8183595	8198290	8200300	8177068
8184393	8198350	8201447	8179499
8184739	8192181	8202313	8177442
8184817	8192250	8203518	8179358
8186470	8194325	8203835	
8186747	8195968	8203857	

Sample Labels: