URGENT FIELD SAFETY NOTICE

FIRMap™ Catheter, 60 mm Basket
Model: AR064060
GTIN: 00810591020024

Abbott Medical
5050 Nathan Lane
Plymouth, MN 55442
USA

April 28, 2022

Dear Abbott Customer,

Abbott is voluntarily recalling four (4) lots of the FIRMap™ Catheter, 60 mm Basket (model: AR064060) due to incorrect product labeling. Both the box and pouch labels of the FIRMap™ Catheter, 60 mm Basket from these 4 lots contain conflicting information (see Figures 1 and 2 below). The product in the box and pouch is a 60 mm device, and the most prevalent product size indicator on the label (the large, bold filled in oval indicating basket size), properly indicates a 60mm basket size.

Specifically, while the label has a large oval prominently indicating the correct 60 mm size, the label shows the following incorrect labeling:

- The GTIN part number listed is incorrect. The barcode is for a 50 mm device (00810591020017) when it should be for the 60 mm device (00810591020024).
- The labeled size is incorrect as seen directly below the catheter image. The text states 50 mm.
- The model number listed is incorrect. It states AR064050 and should state AR064060

Figure 1: Incorrect Label Information

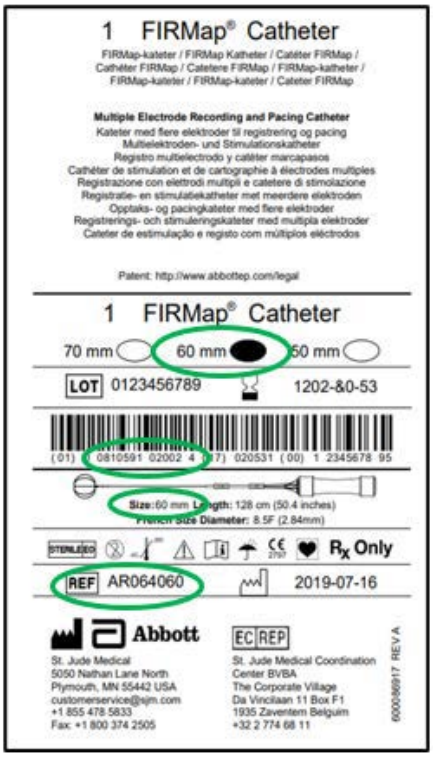

Figure 2: Correct Label

Our records indicate that your institution received product from one or more of the affected lots of model AR064060. The affected lots are listed on Appendix A to this letter. All other lots of FIRMap™ Catheter, 60 mm Basket and any additional models are not impacted and can be used.

Impact and Associated Risks

Based on our initial assessment, if a procedure requires a 60 mm basket and if the labeling error is detected prior to use and interpreted to indicate a 50 mm basket size, the primary risk associated with this labeling error is a short delay to the planned procedure timeframe to replace the product. If a

procedure requires a 60 mm basket and if the labeling error is not detected prior to use or if the labeling error is detected prior to use and the product is used in a procedure requiring a 60 mm basket size notwithstanding the labeling error, the risk for physical harm is low because the device will perform as intended. However, if a procedure requires a 50 mm basket size and the labeling error is detected and interpreted to indicate a 50 mm basket size, there is a low risk of tissue damage.

As of the date of this letter, we have received four (4) customer complaints with no reported adverse patient consequences.

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 credit for returned unused devices.

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.

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

Abbott is committed to providing the highest quality products and support. We thank you for your assistance in this matter and -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	
2156510	2159876
2158303	2162996