URGENT Field Safety Notice

Inquiry™ Steerable Diagnostic Catheter
Model IBI-81474, Lot 8635906
GTIN: 05414734304320

February 2, 2023

Dear Abbott Customer,

Abbott is voluntarily recalling one (1) lot of Inquiry™ Steerable Diagnostic Catheter (Model: IBI-81474) due to incorrect product labeling. Both the box and pouch labels of the Inquiry™ Steerable Catheter from lot 8635906 contain incorrect information indicating that the device contains ten (10) electrodes while the packaged device in fact contains four (4) electrodes. All other aspects of the box and pouch labels are correct.

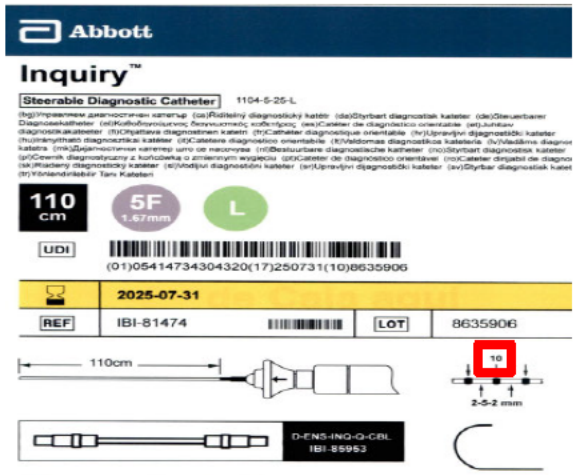

Figure 1: Incorrect Label Information

Figure 2: Correct Label Information

Our records indicate that your institution has received product from the affected lot of Model IBI-81474. All other Inquiry™ Steerable Catheter lots and all other catheter models are not impacted and can be used.

Scope of Problem

The issue is isolated to the specific lot referenced in the table below.

Part Number/UDI	Model Number	Affected Lot
600152332	IBI-81474	8635906

Impact and Associated Risk

Based on Abbott's assessment, it is unlikely that an adverse health consequence will occur due to the labeling error. The product labels (both box and pouch labels) correctly identify the product type as an Inquiry™ Steerable Diagnostic Catheter; however, the labels incorrectly state that the device contains ten (10) electrodes. The number of electrodes on the device is visible through the clear packaging. This error related to the number of electrodes has the potential to result in a short delay to the procedure to replace the product.

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

Actions Requested

Abbott requests that you take the following steps:

- Do not use any remaining inventory from the affected lot.
- Please share this notification with others in your organization, as appropriate.
- Complete and return the Acknowledgment Form to Abbott.
- Return all remaining unused devices from the affected lot to Abbott. Your Abbott Representative can assist you in returning affected devices.
- Contact your local Abbott Representative with any questions related to this issue.

Reporting and Customer Assistance

The appropriate Regulatory Agencies have been notified of this action. Adverse events or quality problems experienced with the use of this product may be reported directly to Abbott as well as to the national competent authority.

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 Electrophysiology