



DEAR CUSTOMER
COMMERCIAL NAME: FIRMap Catheter
Type of Action: Advice regarding use of the device

May 3, 2016

Abbott Electrophysiology (formerly known as Topera GMBH) is sending you this Dear Customer Letter for the FIRMap Catheter, EU-AR064050, EU-AR064060, and EU-AR064070 to notify clinicians of the following:

- Since the first clinical use in October 2013, as of April 18, 2016 Abbott EP has received 16 reports related to a catheter spline fracturing near the distal end of the basket.
- As of April 18, 2016 the incidence rate is <0.4%.
- No patient injuries to date.
- In all cases, the catheter was safely removed without complications.
- A fractured spline is visible under fluoroscopy and/or 3D anatomic mapping during a clinical procedure and should be removed immediately using fluoroscopic guidance to minimize any procedural delay.

Please take the following actions:

1. Review the contents of this letter.
2. Review instructions on how to properly advance and withdraw the catheter as noted in the FIRMap Instructions for Use (L-004):
 - Carefully manipulate the catheter to avoid causing cardiac damage, perforation, or tamponade. Advance the catheter only under fluoroscopic guidance. Appropriate equipment should be available for treatment.
 - Do not advance or withdraw the catheter against excessive resistance.
 - Do not torque the catheter while it is fully deployed.
 - Manual pre-bending of the distal assembly can damage the basket assembly and may cause patient injury.
 - Cardiac mapping procedures should be performed only by physicians thoroughly trained in the electrophysiologic techniques in a fully equipped electrophysiology laboratory.
 - Do not rotate or torque the catheter when basket is collapsed within the delivery sheath.

For additional training on safe catheter handling, please contact your local Abbott EP representative.

Follow the precautions in the FIRMap catheter labeling noted above. Should you observe any catheter with a fractured spline, please notify your local Abbott EP representative or Abbott EP Quality (aepquality@abbott.com or +49 211 52391 366) as soon as possible.

Thank you for your attention to this matter. Abbott EP is committed to providing high quality products and partnering with you to ensure the safety of all patients. If you have any questions about this notice or would like additional training on safe catheter handling, please contact your local Abbott EP representative

