



URGENT Field Safety Notice
For TactiCath™ Quartz Contact Force Ablation Catheter
Model PN-004 065 and PN-004 075
GTIN: 07640157990033 and 07640157990040

May 28, 2020

Dear Abbott Customer,

Abbott's commitment to quality includes informing customers of known data, and we are writing to notify you of a high rate of reported complaints for loss of contact force information while using the TactiCath™ Quartz Contact Force Ablation Catheter.

Scope of Problem

Loss of contact force information during use of the TactiCath™ Quartz Contact Force Ablation Catheter has been reported at a rate of 4.3% (out of 84,104 catheters distributed) over a 26-month period:

- 2985 cases where a single catheter was exchanged due to contact force failure
- 381 cases where 3, 4 or 5 catheters were needed
- 2 cases where the procedure was unable to be completed
- 3 cases of cardiac perforation or tamponade where contact force failure could not be ruled out as a potential cause

When Does it Occur?

- 33% of the reported complaints occurred prior to catheter insertion (complaint rate of 1.4%)
- 67% of the reported complaints occurred during the procedure (complaint rate of 2.9%)

Risk to Patients

Based on Abbott's device risk analysis, loss of TactiCath™ Quartz contact force information could result in:

- Ineffective ablation potentially resulting in an increased risk of AF recurrence or need for repeat procedure
- Potential risks associated with the insertion of a replacement catheter or catheter exchanges such as air embolism, extended exposure to anesthesia and fluoroscopy, infection, and bleeding
- Potential for cardiac perforation and all associated patient harms such as tamponade
- Clinically significant or minor delays in procedure

Recommendations

Abbott recommends the following steps to help prevent TactiCath™ Quartz contact force failures:

- Always cover unused optical cable ports on the TactiSys™ Equipment with the protection cap when not in use
- Carefully disengage the catheter from the packaging tray to avoid damage to the contact force mechanism
- Clean the connectors and carefully secure all connections between the catheter, console and mapping system at the beginning of each procedure (refer to user manual for details)
- Exercise the catheter deflection mechanism and test the force sensor prior to insertion
- When using TactiCath™ Quartz with a steerable sheath, make sure the sheath tip is straight when catheter tip is inserted. Try to keep the steering plane of TactiCath™ Quartz and the sheath aligned to reduce stress on the catheter.



Abbott recommends the following troubleshooting sequence if force sensing is lost prior to or during the procedure:

- Re-check and clean the connections between the TactiCath™ Quartz Catheter, TactiSys™ Equipment and Ensite mapping system (refer to user manuals for details)
- Replace the first failed TactiCath™ Quartz catheter with a second TactiCath™ Quartz catheter
- If two TactiCath™ Quartz catheters fail, consider using different TactiSys™ Equipment for the procedure if available

Returned Product, Reporting, and Customer Assistance

- In the event you experience an issue with the device, we request that the device be returned for investigation, and a replacement device will be provided. Your local Abbott Representative can provide you with a return kit.
- Adverse reactions or quality problems experienced with the use of this product may be reported directly to Abbott.
- Should you have questions about this issue, please contact your local Abbott Representative.

Please know that Abbott is committed to providing the highest quality products and support, and we thank you for assisting us with this process.

Sincerely,