



**Urgent Field Safety Notice**  
**Amplatzer™ TorqVue™ LP (TVLP) System (80cm)**  
**Model 9-TVLP4F90/080, Lot 7406296**  
GTIN: 00811806011578

March 8, 2021

Dear Abbott Customer,

This letter is to inform you of a medical device retrieval affecting one (1) lot of the 80 cm Amplatzer™ TorqVue™ LP (TVLP) system, Model 9-TVLP4F90/080 lot 7406296. The system was packaged with a 60cm delivery catheter rather than the intended 80cm delivery catheter as indicated by the packaging label. All other contents within the package are correct.

To date, Abbott has received four (4) complaints from two (2) healthcare facilities and two (2) distributors in association with four (4) occurrences linked to the affected lot. Due to the shorter length of the catheter, use of the affected product may result in difficulty establishing deployment positioning leading to a potential delay in procedure. There have been no reports of serious harm to patients due to the affected lot.

**Customer Actions:**

Our records indicate your institution received product from the affected lot. As a result, Abbott requests that you take the following actions:

- Identify and quarantine any unused inventory from the affected lot.
- Promptly return all unused affected product to Abbott. Your local Abbott Representative can assist you in the return and replacement of this product and ensure that the necessary forms are completed.

Please distribute this notice to those who need to be aware within your organization. We ask that you maintain a record of this notice to ensure effectiveness of the communication.

Should you have any questions about this issue or for order replenishment, please contact your local Abbott Representative.

The appropriate Regulatory Agencies have been notified of this action.

We sincerely apologize for any inconvenience this may cause. Abbott is committed to providing the highest quality products and support, and we thank you for assisting us with this process.

Sincerely,

A handwritten signature in black ink that reads 'Kara Carter'.

Kara Carter  
Divisional Vice President, Quality  
Abbott Structural Heart