



URGENT MEDICAL DEVICE RECALL

9-TVLP4F90/060, 9-TVLP4F90/080, 9-TVLPC4F90/080

Structural Heart
Abbott Laboratories, Inc.
5050 Nathan Lane
Plymouth, MN 55442 USA

March 2025

Dear Valued Customer,

Abbott is voluntarily recalling certain 4F Amplatzer™ TorqVue™ LP Delivery System (TVLP) and 4F Amplatzer™ TorqVue™ LP Catheter (TVLPC) devices, which were impacted by a manufacturing anomaly (referred to as “Impacted Lots”). You are receiving this letter because our records indicate that unit(s) from the Impacted Lot(s) listed in Appendix A were consigned or sold to your facility. Any Impacted Lots which have not yet been consumed should be returned to Abbott. All other lots in your inventory are not affected and can continue to be used. To date, there have been no reports of patient harm associated with devices from the Impacted Lots.

As background, Abbott has received four (4) customer reports of a small leak in the shaft for the 4F Amplatzer™ TVLP device, which resulted in device exchange, or a decision not to perform an angiogram to assist with occluder placement and instead to rely exclusively on echocardiography and fluoroscopy. Investigation of returned devices identified a small breach in the proximal end of the shaft under the strain relief of the delivery system. The breach was inadvertently imparted through a molding process during manufacturing. The manufacturing process has been corrected and no additional lots outside of those associated with this notification are impacted.

The leak is not visibly detectable due to being located under the strain relief but may potentially be detected during preparation when flushing or aspirating. In the event the leak is not detected until after catheter insertion into the vasculature, the procedure may be prolonged due to the need to replace a leaking catheter. In rare circumstances, blood loss or air ingress with the potential for an air embolism may occur whenever the leak is not noticed during preparation or de-airing. However, this scenario is considered unlikely to occur due to the small size of the leak and the tight fit of the heat-shrunk strain relief, which limits air/fluid flow.

As these catheters are single-use products, nothing further is needed for Impacted Lots which have been consumed.

Steps Abbott is Requesting You to Take:

- Share this notice with applicable personnel within your institution.
- Return any remaining unused devices from Impacted Lots listed in Appendix A. Your Abbott representative will assist you in this activity and will facilitate inventory replenishment.
- Complete and return the accompanying Acknowledgement Form to Abbott.

Abbott is informing all applicable regulatory agencies about this matter. Adverse events or quality problems experienced with the use of the Impacted lots may be reported directly to Abbott. Reports may also be sent to the FDA's MedWatch Adverse Event Reporting program by completing Form FDA 3500 online at www.FDA.gov, calling 1-800-FDA-1088 to report by telephone or faxing 1-800-FDA-0178.

If you have any questions, please contact your local Sales Representative or Abbott Support at 1-800-544-1664.

We sincerely apologize for any inconvenience that this may cause. Please know that Abbott is committed to providing the highest level of support, and we thank you for assisting us with this process.

Sincerely,

A handwritten signature in black ink that reads 'C. Gallivan'.

Christopher Gallivan
Divisional Vice President, Quality
Abbott Structural Heart



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 Abbott Laboratories, Inc.
 5050 Nathan Lane
 Plymouth, MN 55442 USA

Appendix A: Affected Product List

Model: 9-TVLP4F90/060
9114256
9125090
9141186
9157327
9211450
10005333
10079342
10080103
10092488
10092499
10092519
10212158
10248201
10263748
10333989
10334851
10353324
10372738

Model: 9-TVLP4F90/080		
9016063	9244572	10174818
9016064	9244573	10175447
9016066	10005331	10176817
9022842	10005332	10226050
9022844	10019418	10227816
9028128	10037338	10227817
9035067	10037345	10239207
9042409	10037349	10239212
9043747	10037350	10246785
9044442	10040007	10246788
9055896	10040008	10248202
9056311	10040010	10248203
9066021	10064658	10254186
9081582	10064659	10259337
9095598	10068340	10263341
9102677	10068341	10263346
9123302	10068342	10263749
9123306	10068344	10270061
9123307	10080105	10270065
9141189	10092470	10277295
9152705	10092496	10295046
9159621	10092497	10295102
9173254	10121849	10296780
9179166	10126315	10296820
9182131	10137280	10306815
9182137	10138762	10306828
9188479	10151051	10316876
9205604	10161379	10316888
9206150	10161381	10333527
9206762	10161383	10333528
9208479	10172908	10340533
9212521	10172909	10341801
9230598	10172912	10345596

Model: 9-TVLPC4F90/080	
8976622	10004075
8976626	10004078
8979271	10011461
8979276	10011462
9002888	10011463
9002937	10011465
9061627	10017790
9078966	10017792
9093895	10080355
9134623	10196106
9134626	10196119
9144113	10198795
9144123	10198801
9148110	10198877
9148579	10198878
9148584	10198889
9155868	10207472
9158088	10207503
9158302	10219398
9240174	10219400
9241591	10219401
9241593	10246781
9241596	10269957
9241598	10271039
9249886	10274454
9249889	10274757
9249910	10283818
10004059	10283878
10004071	10299328
10004072	10299329