MEDICAL DEVICE RECALL

Amplatzer™ Steerable Delivery Sheath

Model: ASDS-14F-075
GTIN: 05415067036025

Abbott Structural Heart
Abbott Medical
5050 Nathan Lane
Plymouth MN 55442 USA

June 2023

Dear Abbott Customer,

Abbott is voluntarily recalling the Amplatzer™ Steerable Delivery Sheath (Model ASDS-14F-075) ("ASDS product") due to the potential for air embolism during normal use conditions. Our records indicate that your institution received the ASDS product, and we are requesting that you return any unused ASDS product to Abbott. Our sales force will work with you to facilitate this process.

Why the Product is Being Recalled
Abbott has observed an overall reported incidence rate of 0.77% related to observed or potential air embolism during procedures in which the ASDS product was used. Within those cases, customers have reported air emboli having resulted in transient ST segment elevation resolving spontaneously and, less commonly, hemodynamic instability requiring medical intervention. There have been no reported cases of permanent injury or fatality due to air embolism.

The Instructions for Use indicate that "the hemostasis valve in the closed position minimizes blood loss but does not prevent air ingress" and provides instructions which reduce the potential for air ingress. Due to the continued occurrence of air ingress events, Abbott has decided to recall the ASDS product pending the approval and release of a modified steerable product. Importantly, please note that this issue is specific to the hemostasis valve of the ASDS product and does not impact the Amplatzer™ Amulet™ Left Atrial Appendage Occluder implant.

Steps Abbott is requesting you to take:

- Return any remaining unused ASDS product to Abbott. Your Abbott representative can assist you in returning these devices.
    - Continue to use the fixed curve TorqVue™ 45°x45° delivery system for future Amplatzer™ Amulet™ Left Atrial Appendage Occluder implants.
- Complete and return the accompanying Acknowledgment Form to Abbott.

The applicable Regulatory Agencies have been notified of this action. Adverse events or quality problems experienced with the use of the ASDS product may be reported directly to Abbott or to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. To submit your report:

- Complete the voluntary Form FDA 3500 online;
- Call 1-800-FDA-1088 to report by telephone; or
- Download the form from FDA.gov or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form or submit by fax to 1-800-FDA-0178 (Send only page 1 plus any continuation pages - do not send instruction pages).

Should you have questions about this issue, please contact your local Abbott Representative or Abbott Support at 1-800-544-1664 (Option 2) (U.S.), 7:00 a.m. - 7:00 p.m. Central Time, Monday through Friday.

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 with this process.

Sincerely,

Christopher Gallivan
Divisional Vice President, Quality
Abbott Structural Heart